**PUBLIC VERSION**

# *MEXICO – MEASURES CONCERNING GENETICALLY ENGINEERED CORN*

**(MX-USA-2023-31-01)**

## REBUTTAL SUBMISSION
## OF THE UNITED STATES OF AMERICA

**April 2, 2024**

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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) |
| CCPR | Codex Committee on Pesticide Residues |
| CEC | Commission for Environmental Cooperation |

[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*."

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|---|---|
| CGIAR | Consortium of International Agricultural Research Centers |
| CIBIOGEM | Inter-Secretarial Commission on Biosafety of Genetically Modified Organisms |
| CIMMYT | International Maize and Wheat Improvement Center |
| Codex | Codex Alimentarius Commission |
| Codex Guidelines | *Guideline 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 |
| CONAHCYT | National Council of Science and Technology |
| CONAHCYT Dossier | "Scientific Dossier on Glyphosate and GM Crop" |
| 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 |
| IARC | International Agency for Research on Cancer |
| IPPC | *International Plant Protection Convention* |
| ISAAA | International Service for the Acquisition of Agri-biotech Applications |
| JMPR | Joint FAO/WHO Meeting on Pesticide Residues |
| LMOs | Living modified organisms |
| MRL | Maximum residue level |
| Party | USMCA Party |
| PDP | Pesticide Data Program |
| SADER or SAGARPA | Mexican Secretariat of Agriculture & Rural Development |
| SALUD or SSA | Mexican Secretariat of Health |
| SHCP | Mexican Secretariat of Finance and Public Credit |
| SEMARNAT | Mexican Secretariat of the Environment and Natural Resources |
| SNIB | National Biosafety Information System |
| 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 |

## TABLE OF EXHIBITS

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# I. INTRODUCTION

1. For decades, the international scientific community has regarded GE crops as safe for human consumption and safe for animal and plant life and health. Mexico was a part of this community. Then—with no new science and with a renewed commitment in the form of USMCA to use a science-based and risk-based approach to SPS issues—Mexico adopted its *Decree Establishing Various Actions Regarding Glyphosate and Genetically Modified Corn* ("2023 Corn Decree"), and included within it a ban on GE corn for use in dough and tortillas and an instruction to gradually displace imports of GE corn for use in animal feed and industrial use for human consumption. There was no scientific basis for this abrupt change, and so there was no justification under Mexico's USMCA obligations.

2. Mexico, now faced with defending measures that in design and effect fail to serve legitimate ends, employs an approach that is often vague and imprecise in identifying risks, attempts to pull together after-the-fact necessary pre-cursors like a risk assessment, selectively chooses articles to distract from prevailing scientific opinion under international standards, and resorts to lengthy detours that have no relevance to the U.S legal claims. In this Rebuttal Submission, the United States will do its best to untangle the issues and correct Mexico's factual and legal errors. But at bottom, Mexico cannot escape that it took an approach that abandoned science, as summarized by the 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:[3]

> [T]here is no[t] a 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.

The pivot to this approach did not just jettison the scientific evidence and science-based regulation; it breached several provisions of the USMCA.

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[3] Biotechnology Committee of the Mexican Academy of Sciences, TRANSGENICS. MAJOR BENEFITS, ABSENCE OF HARMS AND MYTHS, at 28 (2017), http://coniunctus.amc.edu.mx/libros/TransgenicosCoordinadorFBolivar.pdf (hereinafter "Biotechnology Committee of the Mexican Academy of Sciences") (Exhibit USA-37); *id.* at 24 (calling GE organisms "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).

3. Mexico devotes a substantial portion of its factual background—and associated legal arguments—to addressing cultivation of corn in Mexico and alleged harms from the general application and use of glyphosate (*e.g.*, spraying), neither of which is relevant to this dispute.[4]

4. As the United States stated in its Initial Submission and made clear in its request for establishment of a panel,[5] the two measures from Mexico's *Decree Establishing Various Actions Regarding Glyphosate and Genetically Modified Corn* ("2023 Corn Decree") that are at issue in this dispute are:

(i) The Tortilla Corn Ban. Mexico's ban on the importation and sale of GE corn for nixtamalization or flour production, which operates in conjunction with Mexico's authorization process for the importation and sale of GE food products, *not* intended for cultivation.[6]

(ii) The Substitution Instruction. Mexico's instruction to gradually substitute GE corn used for animal feed and industrial use for human consumption, which

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[4] *See, e.g.*, Initial Written Submission of the United Mexican States ("Mexico's Initial Submission"), Sections V.A (Agriculture in Mexico) (discussing cultivation of corn in Mexico); *id.*, Sections V.D.1-2 (discussing the purported relationship between GE corn and glyphosate). For example, the section titled "Effects of GM corn and its technological package on biodiversity and the environment" talks about glyphosate exposure through means other than dietary consumption, let alone dietary consumption of GE corn. *See id.*, Section V.D.1.c. The section titled "The relationship between GM corn and glyphosate" cites studies that in fact are about glyphosate exposure through spraying and means other than dietary consumption (let alone GE corn consumption). *Id.*, Section V.D.2.a. Mexico alleges that "human exposure to glyphosate is widespread and constant" and then cites a three-sentence article that says nothing about glyphosate—*see* MEX-188—along with a variety of other articles that discuss glyphosate exposure through means other than dietary consumption. The section on "Health effects of glyphosate exposure" suffers from similar issues and does not address (nor is it relevant to) GE corn consumption. *See* Mexico's Initial Submission, Section V.D.2.b.1. The section titled "The relationship between glyphosate and GM corn and its impact on native varieties of corn in Mexico" likewise is all about glyphosate application and is not pertinent to this dispute. *See* Section V.D.2.c. Prohibiting the importation of GE corn (for certain end uses or more broadly) would not address any of the issues posited in these articles.

[5] *See* U.S. Request for Establishment of a Panel, paras. 1-2 (Aug. 17, 2023), https://ustr.gov/sites/default/files/2023-08/US%20Panel%20Request%20-%20Mexico%20Biotech.pdf.

[6] This legal regime governing the importation and sale of GE products other than for cultivation is set out in the *Biosafety Law of Genetically Modified Organisms* ("Biosafety Law") (Exhibit USA-85), in particular Articles 1-8, 91-98, and 119-122, and in the *Regulations to the Genetically Modified Organisms Biosafety Law* ("Biosafety Regulations") (Exhibit USA-86), in particular Articles 1-4 and 23-32. *See also* Initial Submission of the United States of America ("U.S. Initial Submission"), Section V.A.1 (defining the Tortilla Corn Ban). The United States has previously referred to the Tortilla Corn Ban as a "set of measures" because Article 6(II) of the 2023 Corn Decree operates in conjunction with the Biosafety Law and Biosafety Regulations. However, for ease of comprehension, the United States uses the singular "measure" to refer to the Tortilla Corn Ban. The same is true with respect to the Substitution Instruction.

operates in conjunction with Mexico's authorization process for the importation and sale of GE food products, ***not*** intended for cultivation.[7]

5. Both measures concern Mexico's treatment of imported GE corn products, which are authorized precisely with the condition that these products are ***not*** intended for planting.[8]

6. The United States is not challenging Article 6(I) of the 2023 Corn Decree ("cultivation ban"), concerning the prohibition on issuing permits for the release of GE corn seeds into the environment in Mexico, which is subject to an entirely separate licensing process.[9]

7. The United States also is not challenging Mexico's measure to revoke and refrain from issuing authorizations and permits for the importation and use of glyphosate ("glyphosate ban"), which is reflected in Articles 3 through 5 of the 2023 Corn Decree, and concerns an entirely different regulatory process related to pesticide registration in Mexico.[10]

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[7] 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. *See also* U.S. Initial Submission, Section V.A.2 (defining the Substitution Instruction).

[8] In Mexico, a person is liable for an "administrative infraction" if that person knows that a product is a GE product and 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. Biosafety Law, art. 119(I)-(II) (Exhibit USA-85). These infractions are punishable by a fine of 1,501 to 30,000 days of the general minimum salary in force in Mexico City. *Id.*, art. 120(II) (Exhibit USA-85).

[9] *Compare* Biosafety Law, Title 2, Chapters 2-3 (concerning permits for release of GE seeds) *with* Title 5, Chapter 1 (concerning authorizations of GE products for food and feed uses) (Exhibit USA-85); *compare* Biosafety Regulations, Title 2 (concerning permits for release) *with id.*, Title 3 (concerning authorizations for food and feed uses) (Exhibit USA-86).

[10] In any event, as of March 26, 2024, Mexico has postponed implementation of the glyphosate ban. *See* A. Harrup, "Mexico Temporarily Postpones Glyphosate Ban Until Substitute Found," *DowJones Newswires* (Mar. 27, 2024) (Exhibit USA-239). This decision came after Mexican government officials from both the ruling political party, Morena, and the opposition party submitted "Points of Agreement" urging the Mexican President and other Federal agencies to reconsider the 2023 Corn Decree's glyphosate ban, noting that glyphosate "has a history of over 40 years of safe use and has been extensively evaluated by institutions and regulators in more than 160 countries through thousands of studies." Morena Party Point of Agreement, at 4 (Mar. 13, 2024) (English version) (further stating that "glyphosate is probably the most studied active substance in the world" and detailing studies) (Exhibit USA-184); *id.* at 5-6 ("Based on the vast amount of scientific evidence demonstrating the safety of glyphosate for agriculture, it is authorized by the most stringent regulatory agencies worldwide[.]") (Exhibit USA-184); Institutional Revolutionary Party Point of Agreement, at 3 (Mar. 6, 2024) (English version) ("Glyphosate has become the most used herbicide around the world due to its efficacy, safety, cost-effectiveness, and other benefits.") (Exhibit USA-185); *id.* at 7 ("[B]ased on a rigorous examination of over 2,400 scientific studies, the European Food Safety Authority (EFSA) has concluded that glyphosate does not represent a risk to human or animal health or to the environment, and, given the exhaustive nature of the study, different future results are unlikely." (citation omitted)) (Exhibit USA-185).

8. Mexico, in its Initial Submission, has cited a multitude of articles in an after-the-fact attempt to find some basis to justify the measures at issue.[11] However, as the United States will explain in this Rebuttal Submission, these articles are largely irrelevant to assessing the disputed measures and do not demonstrate the alleged risks to human, animal, or plant life or health that Mexico claims to be addressing. In fact, most of the articles that Mexico has put forward in its Initial Submission do not even appear in the "risk assessment" on which Mexico, for the first time, claims the 2023 Corn Decree is based. Now forced to justify its measures in this legal dispute, Mexico has endeavored to cobble together "scientific" support that only reinforces that Mexico's Tortilla Corn Ban and Substitution Instruction are not, and never have been, based on science- or risk-based principles and contradict the international standards, guidelines, and recommendations relevant to human, animal, and plant life and health.

9. Now that both disputing Parties have presented their Initial Submissions to the Panel, it is important to note numerous issues that are not in dispute:

10. ***First***, the Parties do not dispute that the Tortilla Corn Ban is intended to accomplish certain objectives in Annex A, paragraphs 1(a)-(b) of the World Trade Organization ("WTO") *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement"), incorporated by reference into the *United States-Mexico-Canada Agreement* ("USMCA"), and therefore properly constitutes an SPS measure.[12]

11. ***Second***, Mexico does not dispute that it has not performed a risk assessment on which the Substitution Instruction is based.[13]

12. ***Third***, Mexico confirms that, for the Substitution Instruction, it has not defined an appropriate level of protection ("ALOP") for human health, notwithstanding this measure specifically orders government agencies to eliminate the use of GE corn in industrial use for human consumption and in animal feed.[14]

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[11] *See infra* Sections II.A, IV.A.2, IV.E.

[12] Mexico's Initial Submission, paras. 323, 326.

[13] Mexico's Initial Submission, para. 359 (confirming that Mexico has not conducted a risk assessment "[a]t this stage"); *see infra* Section IV.A (addressing Mexico's breach of Article 9.6.3 of the *United States-Mexico-Canada Agreement* ("USMCA")).

[14] Mexico's Initial Submission, para. 344; *see infra* Sections IV.A-B (addressing Mexico's breach of Articles 9.6.3 and 9.6.6(a) of the USMCA).

13. *Fourth*, Mexico does not contest that the Substitution Instruction is not based on relevant scientific principles, and therefore does not rebut the alleged inconsistency with Article 9.6.6(b) of the USMCA.[15]

14. *Fifth*, Mexico does not dispute that it did not document its risk management process for the Tortilla Corn Ban or the Substitution Instruction, or that it did not permit Members to comment on such process, as required under Article 9.6.7 of the USMCA.[16]

15. In light of these uncontested items, only the following issues remain before the Panel:

16. *First*, as the United States reaffirms in Section III, *infra*, the Substitution Instruction is an SPS measure as defined in the USMCA and thus subject to the disciplines of Chapter 9.

17. *Second*, the Tortilla Corn Ban breaches Article. 9.6.3 of the USMCA, for each of the following reasons:

(i) Mexico failed to define its human and plant health ALOPs (concerning risks from consuming GE corn and risks from transgenic introgression of native corn, respectively) with adequate specificity;

(ii) the measure is not based on the international standards relevant to human and plant life or health; and

(iii) even assuming no relevant international standards apply to meet Mexico's alleged ALOPs, Mexico did not conduct an appropriate risk assessment on which the Tortilla Corn Ban is based.[17]

18. *Third*, the Substitution Instruction breaches Article 9.6.3 of the USMCA for each of the following reasons:

(i) Mexico failed to define its plant health ALOP with adequate specificity; and

(ii) the Substitution Instruction is not based on the international standards relevant to plant life or health.[18]

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[15] Mexico's Initial Submission, Section VII.E.6 (only addressing the Tortilla Corn Ban and not the Substitution Instruction).

[16] *See* Mexico's Initial Submission, Section VII.E.3 (only addressing Mexico's alleged risk assessment process and making no mention of a documented risk management process); *infra* Section IV.D (addressing Mexico's inconsistency with Article 9.6.7 of the USMCA).

[17] *See infra* Section IV.A.

[18] *See infra* Section IV.A.

As noted above, Mexico does not dispute that (i) it has not identified a human health ALOP for the Substitution Instruction and (ii) it has not conducted a risk assessment on which this measure is based, each of which contravenes Article 9.6.3 of the USMCA.

19. *Fourth*, the Tortilla Corn Ban and the Substitution Instruction, respectively, are applied beyond the extent necessary to achieve Mexico's alleged SPS objectives under Article 9.6.6(a) of the USMCA, because there are less trade-restrictive means available that would actually contribute more to Mexico's stated objectives than the measures at issue.[19]

20. *Fifth*, the Tortilla Corn Ban is not based on relevant scientific principles and therefore is inconsistent with Article 9.6.6(b) of the USMCA. As noted above, Mexico does not contest that the Substitution Instruction is not based on relevant scientific principles.[20]

21. *Sixth*, Mexico has no documented risk assessment for either the Tortilla Corn Ban or the Substitution Instruction, and did not afford other parties the opportunity to comment on any such documents, thereby breaching Article 9.6.7 of the USMCA. As noted above, Mexico does not dispute that it has already failed to meet certain obligations under this Article, namely that it did not document its risk management process for the disputed measures, nor did Mexico permit Members to comment on such a process.[21]

22. *Seventh*, Mexico did not take into account relevant international standards or available relevant scientific evidence when adopting the Tortilla Corn Ban and the Substitution Instruction, respectively, such that each measure is inconsistent with Article 9.6.8 of the USMCA.[22]

23. *Eighth*, the Tortilla Corn Ban and the Substitution Instruction, respectively, are more trade-restrictive than required to achieve Mexico's alleged ALOPs for human or plant life or health and thus each measure breaches Article 9.6.10 of the USMCA.[23]

24. *Ninth*, the challenged measures prohibit or restrict the importation of GE corn from the United States into Mexico and consequently contravene Article 2.11 of the USMCA.[24]

25. Having failed to meet its commitments under the USMCA, Mexico's defense relies on certain exceptions under Article XX of the *General Agreement on Tariffs and Trade 1994* ("GATT 1994"), arguing that the measures are necessary to protect "public morals"—described

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[19] *See infra* Section IV.B.

[20] *See infra* Section IV.C.

[21] *See infra* Section IV.D.

[22] *See infra* Section IV.E.

[23] *See infra* Section IV.F.

[24] *See infra* Section V.

as Mexico's native corn, the milpa, biocultural wealth, and gastronomic heritage—and relate to "the conservation of exhaustible natural resources."[25]

26. While the United States acknowledges that Mexico has a deep appreciation for its native corn varieties and related agriculture, the measures at issue in this dispute do not serve the ends that Mexico has put forward in its Initial Submission. Even aside from this disconnect, there would be less trade-restrictive measures available to meet and fulfill these objectives of protecting public morals or conserving exhaustible natural resources. Accordingly, Mexico's reliance on these defenses is unavailing.

27. Similarly, Mexico's invocation of Article 32.5 of the USMCA, concerning indigenous people's rights, fails because Mexico has not demonstrated that the challenged measures are not a means of arbitrary or unjustified discrimination against persons of the other Parties or a disguised restriction on trade. Further, as the United States will demonstrate in this Rebuttal, should the Panel find—contrary to the ample evidence before it—that the challenged measures are not inconsistent with Mexico's USMCA commitments due to the applicability of this exception, the United States alternatively asserts that it had a reasonable expectation at the time the USMCA was concluded that trade in GE corn would continue without Mexico adopting these measures, such that the Tortilla Corn Ban and the Substitution Instruction are causing nullification or impairment within the meaning of Article 31.2 of the USMCA.

28. At bottom, Mexico, consistent with its USMCA commitments, was required to adopt or maintain SPS measures that are based on science- and risk-based principles.[26] As the United States explained in its Initial Written Submission, and will explain further in this Rebuttal, in adopting the Tortilla Corn Ban and the Substitution Instruction, Mexico breached these core tenets of the SPS Chapter of the USMCA, and, in addition, breached Article 2.11 of the USMCA. Mexico has failed to demonstrate otherwise in its Initial Submission.

## II. MEXICO'S FACTUAL BACKGROUND CONTAINS SIGNIFICANT ERRORS.

29. Mexico devotes over 40 percent of its Initial Submission to what it labels "Factual Background," divorced from any legal arguments. Where relevant to legal arguments, the United States rebuts the errors in Mexico's factual section in the appropriate U.S. legal sections below (Sections III and IV). However, there are a great deal of factual assertions that are incorrect regarding the purported risks of GE corn, and indeed reflective of Mexico's sharp turn away from legitimate science in this space. To be clear from the outset, particularly given the volume on such errors, the United States addresses up front in Section III.A the most significant errors related to the purported risks of GE corn. Furthermore, Mexico makes erroneous factual assertions that, while not actually relevant to this Panel's resolution of U.S. legal claims, should

[25] *See* Mexico's Initial Submission, Sections VII.J-L.

[26] *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.").

not persist without correction. Therefore, in Sections III.B and III.C below, the United States briefly addresses Mexico's erroneous factual statements regarding the benefits of GE crops and the trade effects of the challenged measures.

### A. Mexico's Factual Background on the Purported Risks of Consuming GE Corn is Inaccurate and Inconsistent with Scientific Principles.

30. In the Factual Background, Mexico appears to allege two primary human health "risks" with respect to consuming GE corn: (i) transgenic proteins; and (ii) glyphosate residues.[27] In addition, Mexico refers to numerous other human health issues, such as purported nutritional deficiencies of GE corn and consumption of "ultra-processed foods," citing to miscellaneous studies.[28] The lack of an actual science-based approach, or valid risk assessment, underpinning these measures surely accounts for some of the ambiguity and imprecision in just what human health risks the measures supposedly address.

31. Throughout the Factual Background, Mexico relies on selected publications to raise the specter of possible safety issues without performing any additional analysis to actually assess whether such observations would warrant a food safety concern.[29] As the United States explains further in Sections IV.A and IV.C simply listing or summarizing a variety of articles to justify an SPS measure does not constitute a risk assessment, nor does it conform to scientific principles under the SPS Chapter of the USMCA.

32. Because Mexico's Factual Background contains extensive errors concerning the alleged adverse human health effects of consuming GE corn, the United States has summarized its observations in Annex I to this Rebuttal Submission.[30] However, at the outset, it is important to

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[27] *See* Mexico's Initial Submission, Section V.D.

[28] *See, e.g.*, Mexico's Initial Submission, paras. 147-151. Mexico also asserts generalized statements of "no scientific consensus" on the safety of GE crop consumption, citing either to articles that do not support the point Mexico is making, to articles that are scientifically unreliable, or to nothing at all. *See, e.g., id.*, para. 88 n.74 (citing MEX-223, which is a "literature review" that identifies no studies where adverse effects were conclusively demonstrated; all conclusions mentioned are that GE organisms are as safe as conventionally bred comparators); *id.*, para. 88 n.75 (purporting that Mexico maintains "scientific compilations and files" that support Mexico's allegations, without specifying the materials); *see also* Annex I (assessing articles cited in Mexico's Initial Submission concerning alleged adverse human health effects from consuming GE corn).

[29] Mexico does not even purport that its Federal Commission for the Protection Against Sanitary Risk ("COFEPRIS")—Mexico's government agency responsible for authorizing GE corn for human consumption in Mexico—has reviewed the studies cited in the Initial Submission, such that this authority has now reached a different conclusion with respect to the GE corn events it previously authorized for food and feed use.

[30] To the extent the United States has not commented on a particular article that Mexico cited in its Initial Submission, such an omission does not imply the United States' endorsement of the article's credibility or relevance.

address some of the most glaring misstatements in Mexico's Factual Background, which capture the non-scientific approach Mexico has chosen to take in adopting the challenged measures:

33. *First*, Mexico spends a large portion of its factual exposition discussing a particular type of GE corn called *Bt* corn and alleges that "GM crops of Bt corn were adopted for commercial planting in the United States, with no evidence on the safety or lack of toxicity of GMOs."[31] This statement could not be further from the truth.[32] The U.S. Environmental Protection Agency ("EPA") has conducted an extensive human health risk assessment for *Bt* proteins that followed the internationally recognized Codex Alimentarius Commission *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* ("Codex Principles"). *Bt* proteins have been used commercially as microbial pesticides in the United States since the early 1960s, which has resulted in a long history of safe exposure.[33] By way of example, the *Bt* varieties frequently cited in Mexico's exhibits—MON810, NK603, MON863—have been subject to numerous safety consultations in the United States,[34] and have been authorized by countries around the world on

[31] *See* Mexico's Initial Submission, paras. 130-134, 182. The document cited (MEX-117) is a letter to the editor, in which the author reports the results of online searches in 1999, with only a handful being scientific studies. The author does not relate what these studies found, much less report any toxic effects.

[32] Furthermore, Mexico conflates *Bt* corn with *Bt* sprays, the latter of which pre-date modern biotechnology and have been used on GE and non-GE plants alike (including in organic agriculture). *See* Mexico's Initial Submission, para. 130.

[33] *Bt* has been widely used as a microbial pesticide for decades, and there have been no confirmed reports of immediate or delayed allergic reactions to Cry proteins despite significant oral, dermal, and inhalation exposure to the microbial product.

[34] *See, e.g.*, "Monsanto Petition to Animal and Plant Health Inspection Service" (Feb. 13, 1995) (Exhibit USA-186); "Monsanto Co.; Addition of Two Genetically Engineered Insect Resistant Corn Lines to Determination of Nonregulated Status," 61 Fed. Reg. 10720 (Mar. 15, 1996) (Exhibit USA-187); FDA, "Biotechnology Consultation Note to the File BNF No. 000034," (Sept. 18, 1996) (Exhibit USA-188); FDA, "Biotechnology Consultation Agency Response Letter BNF No. 000034," (Sept. 25, 1996) (Exhibit USA-189); Monsanto, "Roundup Ready Corn Line NK603" (Jan. 7, 2000) (Exhibit USA-190); "Monsanto Co.; Extension of Determination of Nonregulated Status for Corn Genetically Engineered for Glyphosate Herbicide Tolerance," 65 Fed. Reg. 52,693 (Aug. 30, 2000) (Exhibit USA-191); FDA, "Biotechnology Consultation Note to the File BNF No. 000071" (Oct. 9, 2000) (Exhibit USA-192); FDA, "Biotechnology Consultation Agency Response Letter BNF No. 000071" (Oct. 18, 2000) (Exhibit USA-193); "Petition for Determination of Nonregulated Status for the Genetically Modified Corn Product: Corn Rootworm Protected Corn Event MON863" (May 15, 2001) (Exhibit USA-194); FDA, "Biotechnology Consultation Note to the File BNF No. 000075" (Dec. 31, 2001) (Exhibit USA-195); FDA, "Biotechnology Consultation Agency Response Letter BNF No. 000075" (Feb. 12, 2002) (Exhibit USA-196); "Monsanto Co.; Availability of Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance," 67 Fed. Reg. 65,087 (Oct. 23, 2002) (Exhibit USA-197); EPA, "Biopesticides Registration Action Document - *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material Necessary for Its Production (Vector PV-ZMIR13L) in MON863 Corn (OECD Unique Identifier: MON-ØØ863-5)" (Sept. 2010) (Exhibit USA-198); EPA, "Biopesticides Registration Action Document - Cry1Ab and Cry1F *Bacillus thuringiensis* (*Bt*) Corn Plant-Incorporated Protectants," (Sept. 2010) (Exhibit USA-199). MON863 has not been produced or sold since 2010, when Monsanto elected not to renew that registration. *See also* M. Mendelsohn et al., "Are *Bt* Crops Safe?," 21 NATURE

the basis that these varieties are as safe as their conventional counterparts.[35] Mexico's own regulatory authority—the Federal Commission for the Protection Against Sanitary Risk ("COFEPRIS")—authorized each of these varieties in Mexico and, in doing so, assessed the potential for allergenicity, toxicity and nutritional issues.[36] Mexico has not offered any new analysis from COFEPRIS indicating a need to modify the original assessments, and the associated rationale, nor has Mexico provided an explanation of how countries around the world were wrong in their safety assessments.[37]

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BIOTECHNOLOGY 1003 (Sept. 2003) https://19january2021snapshot.epa.gov/sites/static/files/2015-08/documents/are_bt_crops_safe.pdf (Exhibit USA-200).

[35] *See* Food and Agriculture Organization of the United Nations ("FAO") Genetically Modified ("GM") Foods Platform, MON810 (listing assessments and authorizations in Australia, Brazil, Canada, China, the EU, Indonesia, Kenya, Malaysia, Mexico, New Zealand, Paraguay, the Philippines, South Korea, Singapore, Thailand, Turkey, the United States, Uruguay, and Vietnam) (Exhibit USA-147); FAO GM Foods Platform, NK603 (listing assessments and authorizations in Australia, Brazil, Canada, Colombia, the EU, Indonesia, Iran, Japan, Malaysia, Mexico, New Zealand, Paraguay, the Philippines, South Korea, Russia, Singapore, Thailand, Turkey, the United States, and Uruguay) (Exhibit USA-148); FAO GM Foods Platform, MON863 (listing assessments and authorizations in Australia, Canada, China, Colombia, the EU, Japan, Malaysia, Mexico, New Zealand, South Korea, Russia, Singapore, Thailand, Turkey, and the United States) (Exhibit USA-149). All of these assessments and authorizations were performed in accordance with the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* ("Codex Guidelines"). *See* Codex Guidelines, Annex 3, sec. 3, para. 28 ("Codex Members should make available to a publicly accessible central database to be maintained by FAO information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline[s].") (Exhibit USA-153); *see also* FAO GM Foods Platform, "Welcome to the FAO GM Foods Platform" (explaining that the platform lists safety assessments conducted in accordance with the Codex Guidelines) (Exhibit USA-201).

[36] COFEPRIS Safety Evaluation of NK603 (June 7, 2002) (Exhibit USA-144); COFEPRIS Safety Evaluation of MON810 (Nov. 6, 2002) (Exhibit USA-145); COFEPRIS Safety Evaluation of MON863 (Sept. 29, 2003) (Exhibit USA-146).

[37] Data demonstrating a lack of mammalian toxicity at high levels of exposure confirm the safety of *Bt* corn at levels well above any possible maximum exposure levels anticipated. *See, e.g.*, M. Koch et al., "The Food and Environmental Safety of *Bt* Crops," 6 FRONTIERS IN PLANT SCIENCE 1, 8 (Apr. 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4413729/pdf/fpls-06-00283.pdf (reflecting an acute dose of Cry1Ab protection of 4,000mg/kg/day dosage with no adverse effects on mice, equivalent to an adult consuming approximately 900,000 kg of uncooked *Bt* maize grain in one day) (Exhibit USA-202); *see also* EPA, "Biopesticide Registration Action Document - *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Insecticidal Proteins and the Genetic Material Necessary for Their Production in Corn," at 24, 32 (2008), https://www3.epa.gov/pesticides/chem_search/reg_actions/pip/mon-89034-brad.pdf (Exhibit USA-203); EPA, "Biopesticides Registration Action Document - *Bacillus thuringiensis* Vip3Aa20 Insecticidal Protein and the Genetic Material Necessary for Its Production (via Elements of Vector pNOV1300) in Event MIR162 Maize (OECD Unique Identifier: SYN-IR162-4)," at 39 (2009), https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/decision_PC-006599_3-Apr-09.pdf (Exhibit USA-204); EPA, "Biopesticides Registration Action Document - Cry1Ab and Cry1F *Bacillus thuringiensis* (*Bt*) Corn Plant-Incorporated Protectants," at 26, 36 (Sept. 2010) (Exhibit USA-199); EPA, "Biopesticides Registration Action Document - Modified Cry3A Protein and the Genetic Material Necessary for its Production (Via Elements of

34. *Second*, Mexico alleges a risk of "[h]orizontal transfer of antibiotic resistance transgenes"[38] from consuming GE crops[39]—hypothesizing that humans could acquire certain antibiotic resistance from consuming GE corn—but does not cite a single study showing stable integration of ingested DNA into the DNA of the organism consuming it.[40]

35. *Third*, Mexico alleges nutritional deficiencies of GE corn but does not cite to a single article that addresses nutritional deficiencies in GE corn.[41] COFEPRIS's own safety evaluations of authorized GE events[42] have concluded that there are no substantial nutritional differences between GE corn events and conventional counterparts and are as safe as their conventional counterparts.[43]

36. *Fourth*, Mexico makes vague references to "ultra-processed foods" and conflates these products with GE corn.[44] Genetic engineering has nothing to do with ultra-processed foods, to the extent the latter is even a health issue.[45] To this point, the articles that Mexico cites in relation to alleged health effects from "ultra-processed foods" do not even address GE corn or corn more generally.

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pZM26) in Event MIR604 Corn SYN-IR604-8," at 26 (2010), https://www3.epa.gov/pesticides/chem_search/reg_actions/pip/mcry3a-brad.pdf (Exhibit USA-205); EPA, "Review of Product Characterization and Human Health Data for Plant-Incorporated Protectant Bacillus thuringiensis (Bt) eCry3.1Ab insect control protein and the genetic material necessary for its production in Event 5307 maize (Zea mays) [EPA Reg. No. 67979-EUP-I]," at 7 (May 25, 2010) (Exhibit USA-224).

[38] Mexico's Initial Submission, Section V.D.1.b.3.

[39] "Horizontal transfer" refers to the movement of genetic material between organisms other than by the ("vertical") transmission of DNA from parent to offspring through reproduction.

[40] *See also* Annex I; *infra* Section IV.A.3.b.

[41] *See* Mexico's Initial Submission, Section V.D.1.b.4. Furthermore, all GE corn varieties on the market have been assessed for nutritional safety prior to marketing. *See, e.g.*, FDA, "New Plant Variety Consultations," www.fda.gov/bioconinventory (last accessed Mar. 10, 2024) (Exhibit USA-208).

[42] An "event" refers to a particular crop variety with one or more particular transgenes in specific locations on a chromosome. *See* University of Nebraska, "Glossary of Terms," http://agbiosafety.unl.edu/glossary.htm (Exhibit USA-65).

[43] *See, e.g.*, COFEPRIS Safety Evaluation of MON863 (Sept. 29, 2003) (Exhibit USA-144); COFEPRIS Safety Evaluation of MON810 (Nov. 6, 2002) (Exhibit USA-145); COFEPRIS Safety Evaluation of NK603 (June 7, 2002) (Exhibit USA-146). Developers routinely perform an in-depth compositional analysis to demonstrate that a GE corn event is as nutritious as conventional counterparts. This type of assessment is consistent with the type of analysis called for in the Codex Guidelines. *See* Codex Guidelines, sec. 1, paras., 4, 7 (Exhibit USA-114).

[44] *See, e.g.*, Mexico's Initial Submission, paras. 149-150.

[45] Foods well beyond corn can be ingredients in ultra-processed foods such as wheat, canola, cottonseed, and even sugar, and use of these crops in the production of ultra-processed foods is not something unique or specific to crop varieties derived from genetic engineering.

37. *Fifth*, Mexico's claims that the "safety of GMOs is completely illusory" and "GMOs remain on the market without having been shown to be safe for human consumption" are predicated on two scientific articles from two obscure journals.[46] Mexico ignores the 200-plus different GE corn events that have been authorized by regulators around the world, and the safety assessments supporting these authorizations.[47] Mexico has provided no rebuttal (or risk assessment) in response to these science-based assessments that use an internationally accepted process.

38. *Sixth*, what Mexico calls the "clearest example" of regulatory failure in authorizing GE crops actually refers to a type of corn (StarLink) that *never received* an authorization for use in human food.[48] U.S. regulators determined that the existing evidence was insufficient to establish a reasonable scientific certainty that exposures to the particular pesticidal protein (Cry9C) would be safe for human consumption.[49] Rather than a regulatory failure, this is a key example of the regulatory process effectively working to protect consumers.[50]

39. Placing into stark relief the universe of specious allegations and studies that Mexico has offered to the Panel, the most cited author in Mexico's Initial Submission is Gilles-Eric Séralini, who is considered to be highly unreliable among the scientific community.[51] For example, Mexico refers to "the famous Séralini study" from 2012, alleging "renal deficiencies in rats that ingested grains grown with *Roundup* application (glyphosate-tolerant GM corn NK603)."[52] This study, to the extent it is known, is infamous for being severely flawed on methodological and

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[46] Mexico's Initial Submission, para. 181; *see also* Annex I (assessing MEX-217 and MEX-218).

[47] *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 (Exhibit USA-55).

[48] *See* Mexico's Initial Submission, para. 183.

[49] U.S. Centers for Disease Control and Prevention, "Investigation of Human Health Effects Associated with Potential Exposure to Genetically Modified Corn," at 3, 10 (June 11, 2001), https://www.cdc.gov/nceh/ehhe/cry9creport/pdfs/cry9creport.pdf (further stating that "[t]hese findings do not provide any evidence that the reactions that the affected people experienced were associated with hypersensitivity to the Cry9c protein. . . . Although the study participants may have experienced allergic reactions, based upon the results of this study alone, we cannot confirm that a reported illness was a food-associated allergic reaction.") (MEX-222).

[50] In addition, Mexico makes a very serious—and unsupported—allegation that biotech industry companies are involved in "scientific malpractice and manipulation of information." *See* Mexico's Initial Submission, para. 184. Knowingly providing false data to the U.S. government is a crime. The United States screens its regulators for conflicts of interest to evaluate the data provided by developers.

[51] Mexico's Initial Submission includes at least 11 different Séralini studies. MEX-126; MEX-127; MEX-135; MEX-138; MEX-139; MEX-193; MEX-207; MEX-219; MEX-220; MEX-225; MEX-312. The United States would not typically comment on a specific author, but the overwhelming extent to which this author is cited in Mexico's Initial Submission (more than any other author), and the widespread concerns about this author's reputability, warrant mention.

[52] *See* Mexico's Initial Submission, para. 185.

ethical grounds. The study was widely criticized by scientists and scientific organizations upon publication, including the European Food Safety Agency and Société Française de Pathologie Toxicologique.[53] *Food and Chemical Toxicology*, the journal that published the original article, published dozens of critical responses to the study and ultimately retracted the article after reviewing the author's raw data and concluding that the article did not meet its standards for publication.[54]

40. At bottom, Mexico still has not been able to distance itself from the very clear message of its own Biotechnology Committee of the Mexican Academy of Sciences: "[T]here is no[t] a 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."[55] Mexico claims that this report has been "severely criticized for [its] methodological deficiencies," providing as its only source a statement by a man described as a "lawyer and philosopher" who does not present any scientific critique of the methodology.[56]

41. As the United States will point out throughout this Rebuttal, Mexico presents hypotheses that it posits could be food safety issues—based on a curated selection of dubious articles—but never actually performs the analysis necessary to demonstrate that these are, in fact, food safety concerns that would make GE corn unsafe let alone unsafe to the point that all GE corn would be considered unfit for human consumption. Mexico has put forward no coherent theory or rationale for why GE corn would be unsafe in the face of science-based safety assessments performed by competent authorities using an internationally accepted approach (Codex

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[53] *See, e.g.*, EFSA, "Final review of the Séralini et al. (2012a) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603 as published online on 19 September 2012 in Food and Chemical Toxicology," EFSA JOURNAL (2012), https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2986 (Exhibit USA-209).

[54] "Editor in Chief of *Food and Chemical Toxicology* Answers Questions on Retraction," 65 FOOD & CHEMICAL TOXICOLOGY 394 (2014) (further refuting any undue influence from Monsanto) (Exhibit USA-210); *see also* Annex I (assessing the republished version of this study, MEX-225).

[55] Biotechnology Committee of the Mexican Academy of Sciences, at 28 (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).

[56] *See* Mexico's Initial Submission, para. 234 n.317 (citing MEX-260). Mexico also cites MEX-261 as an alleged criticism of USA-39; Mexico's exhibit is an anonymous blog post by an anti-GE organization that has no scientists on staff. *See id.*

Alimentarius), of which Mexico is a member.[57]

### B. Mexico Misstates the Benefits of GE Crops.

42. In its Initial Submission, Mexico incorrectly asserts there is no link between increasing corn yields and farmer adoption of GE technologies. Mexico also falsely portrays the important global food security role played by countries producing GE corn.[58]

43. Mexico's attempts at refuting improved corn yields and other production benefits of GE corn have no bearing on the legal issues in this dispute, which primarily concern risks (or lack thereof) to human, animal, or plant life or health.[59] Nonetheless, the United States corrects several of Mexico's errors. For example, Mexico cites a study spanning 1961 to 2010 comparing production systems in the United States and Western Europe to purport no differences in yield between GE and non-GE cultivating regions. This study includes 35 years of pre-biotech data to weigh down the trendline toward no difference.[60] There is absolutely no question that crop yields in the United States have increased as a result of GE crops.[61]

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[57] *See* Mexico's Initial Submission, para. 199 (acknowledging Mexico is a Codex member). As the United States explained in its Initial Submission, over 200 different GE corn events have been authorized around the world, at least 70 of which contain a trait for glyphosate tolerance. *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 (Exhibit USA-55). The authorizations were issued in accordance with the Codex Guidelines. *See* FAO GM Foods Platform, "Welcome to the FAO GM Foods Platform" (last accessed Mar. 13, 2024) (Exhibit USA-201).

[58] *See* Mexico's Initial Submission, Section V.B.2.

[59] Mexico also makes the assertion that "the introduction of GM corn would not result in a significant increase in the yield trend compared to hybrid corn." Mexico's Initial Submission, para. 81. Again, it is not clear how this statement is at all relevant to the dispute. However, for context, average global corn yields are around 6 metric ton/hectare (MT/HA). U.S. yields are, on average, 11 MT/HA, and Mexico's yields are 4 MT/HA. *See* USDA Production, Supply and Demand ("PSD") Database, "Corn Yields By Country - 2023 Crop Year - MT/HA Yield" (Exhibit USA-222). Mexico cites one study of an unnamed tropical hybrid against one variety of GE corn to conclude that GE corn will not work in its climate. *See* MEX-064. The findings of this study are a function of the particular GE cultivar selected, which had not been adapted to the climate; a non-GE cultivar not adapted to the tropics would similarly perform less well than locally adapted ones. This study does not mean that GE crops will not work in Mexico's climate.

[60] *See* MEX-062. The United States did not surpass 90 percent GE soybeans until about 2007 and did not surpass 90 percent GE cotton and corn until about 2014, four years after the period examined by the study. *See* U.S. Department of Agriculture ("USDA") Economic Research Service ("ERS"), "Biotechnology," https://www.ers.usda.gov/topics/farm-practices-management/biotechnology/ (last updated Oct. 4, 2023) (Exhibit USA-223). In 1996, when stacked varieties of corn seed (*i.e.*, multiple GE traits) were not yet available, farmers who wanted to plant GE seed had to choose between targeting a specific pest or using an herbicide-tolerant seed variety. In contrast, by 2016, the seed market offered multiple varieties of corn that protected the crop against three or more pathways to potential damage. *See also, e.g.*, W. Klümper & M. Qaim, "A Meta-analysis of the Impacts of

44. In addition, Mexico's suggestion that "there is no widespread preference for GM crops, particularly corn, or for approving its importation," is inaccurate.[62] The leading countries that export corn—the United States, Brazil, and Argentina—grow approximately half of global corn production, and their farmers overwhelmingly (approximately 90 percent) choose to use GE technologies.[63] In 2023, these three countries accounted for 73 percent (147 million metric tons) of globally traded corn.[64] This globally exported GE corn is a critical component of global food security. In the absence of surplus corn production in these countries—surpluses which are enabled by GE technologies—countries importing corn would face greater food insecurity and higher food prices.

45. The United States further addresses Mexico's misleading allegations regarding agrochemical usage on GE crops in Annex II.[65]

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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 reduced the use of pesticides by 37 percent, increased yields by 22 percent, and increased farmers' profits by 68 percent) (Exhibit USA-36); USDA ERS, "Innovations in Seed and Farming Technologies Drive Productivity Gains and Costs on Corn Farms" (Apr. 4, 2022), https://www.ers.usda.gov/amber-waves/2022/april/innovations-in-seed-and-farming-technologies-drive-productivity-gains-and-costs-on-corn-farms/ (Exhibit USA-226).

[61] *See, e.g.*, USDA, National Agricultural Statistics Service, "Corn Yield by Year (U.S.)" (last updated Jan. 12, 2024) (Exhibit USA-225); USDA ERS, "Innovations in Seed and Farming Technologies Drive Productivity Gains and Costs on Corn Farms" (Apr. 4, 2022), https://www.ers.usda.gov/amber-waves/2022/april/innovations-in-seed-and-farming-technologies-drive-productivity-gains-and-costs-on-corn-farms/ ("Corn yields and planted acres have risen substantially in recent decades as farmers have adopted new technologies, particularly genetically engineered seeds and precision farming systems, that have supported higher yields and expansion into new areas.") (Exhibit USA-226).

[62] *See* Mexico's Initial Submission, paras. 85-87. These broad claims also imply that if a country does not import GE products then they must be banned, which is not true. Mexico appears to be equating those countries that do not have functioning event approval systems with those that have prohibited imports.

[63] *See* USDA PSD Database & USDA Foreign Agricultural Service ("FAS"), "Corn Statistics - Top Producers and Exporters (plus Mexico)" (Exhibit USA-227).

[64] USDA PSD Database, "Corn Exports By Country - 2023 Crop Year" (Exhibit USA-228).

[65] *See* Mexico's Initial Submission, Section V.B.2.b (titled "The amount of agrochemicals used has increased"); *see also* U.S. Initial Submission, paras. 26-28. Mexico's statements in Section V.B.2.b of its Initial Submission are highly generalized in nature, remarking on the number of glyphosate-tolerant events on the market, and do not address alleged glyphosate residues on imported GE corn (*i.e.*, the actual risk that Mexico purports to be of concern).

### C. Mexico Erroneously Argues that the Challenged Measures Do Not Impact Current Trade.

46. At various points in its Initial Submission, Mexico makes assertions about the supposed absence of current trade effects resulting from the challenged measures.[66] No U.S. claim requires establishing the existence of trade effects, and the United States already detailed in its Initial Submission how the Tortilla Corn Ban and the Substitution Instruction may directly or indirectly affect trade between the Parties such that these measures are subject to the SPS disciplines of the USMCA.[67]

47. Nevertheless, for the sake of accuracy, the United States briefly explains in this section that the challenged measures are certainly ***not*** without impact.

48. As an initial matter, the text of the measures on its face makes clear their impact on trade. There is no argument that the Tortilla Corn Ban makes it illegal to import GE corn for use in dough and tortillas.[68] Similarly, the Substitution Instruction orders the phasing out of imported GE corn for other uses. Mexico's decision not to define the exact timing in which the gradual substitution will be carried out does not eliminate international trade impacts. As the United States explained in its Initial Submission, 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

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[66] *See* Mexico's Initial Submission, paras. 2, 19; *see also id.*, Sections V.G, VI.B.

[67] *See* USMCA, art. 9.2 ("This Chapter applies to all sanitary and phytosanitary measures of a Party that may, directly or indirectly, affect trade between the Parties."); *see also* U.S. Initial Submission, paras. 93-96, 103-107. A previous World Trade Organization ("WTO") panel made the same point in an equivalent context. *See* Panel Reports, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 7.435 (adopted Nov. 21 2006) ("[I]t is not necessary to demonstrate that an SPS measure has an actual effect on trade.") (hereinafter "Panel Reports, *EC –Approval and Marketing of Biotech Products*") (Exhibit USA-104).

[68] Mexico concedes that "Article 6.2 establishes a restriction on the end use of GM corn grain in Mexico for direct human consumption" but contends that "none of the existing authorizations have been revoked, amended or otherwise modified." Mexico's Initial Submission, para. 318. Mexico further states that the Biosafety Law permits the suspension or revocation of authorizations "when there is a change in the circumstances of the activities that may influence in the result of the state of the assessment of the possible risks on which the permit was based, or when there is additional scientific information that could modify any of the conditions, limitations or requirements of the permit." *Id.*, para. 265. If Mexico contends that these Biosafety Law provisions have not been invoked, then Mexico concedes that there is no change in scientific information or circumstances to warrant a modification or revocation of the authorizations. Further, it is not clear what would justify inclusion of the end-use restriction in new authorizations but not existing authorizations.

key export markets.[69] Seed companies, farmers, and traders are unable to plan efficiently for forthcoming growing seasons. Both the quantity and variety of crops grown impact trade.

49. In addition to the uncertainty already created by the Substitution Instruction—and any present effects that flow therefrom—the measure's future impacts on trade are also obvious. Mexico contends that the Substitution Instruction does not establish that COFEPRIS must discontinue issuing authorizations for GE corn once the Substitution Instruction is completed.[70] But, to state the obvious, once the substitution is carried out, there would be no permissible uses left under Mexico's authorization regime in the Biosafety Law, as the substitution effectively applies to all other forms of human consumption and animal feed not already covered by the Tortilla Corn Ban. And the traded GE corn is precisely what Mexico will have substituted through government direction.

50. Moreover, Mexico's attempts to explain away trends in import volumes are unavailing. U.S. exports of white corn significantly declined year-on-year in 2023. Without citing any support, Mexico alleges that the decline is [redacted][71] but that statement is inaccurate. In the eleven months that elapsed since the enactment of the 2023 Corn Decree (March 2023 through January 2024, *i.e.*, the latest trade data available) U.S. white corn exports to Mexico, by volume, have declined by approximately 40 percent year-on-year and by 50 percent in total value as a result of Mexico's measures restrictions on GE corn.[72]

51. Anecdotal evidence confirms the impacts. [redacted]

52. Both the Substitution Instruction and the Tortilla Corn Ban impact trade between the United States and Mexico, and Mexico's statements to the contrary are neither legally relevant nor consistent with the evidence.

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[69] *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).

[70] Mexico's Initial Submission, para. 281.

[71] *See id.*, para 241. It is unclear on what basis Mexico has invoked the confidentiality provisions of the USMCA with respect to this generic and unsubstantiated statement; the United States believes that this confidentiality marking should be removed, as "market conditions" are already in the public domain. *See* USMCA, Rules of Procedure for Chapter 31 (Dispute Settlement), art. 19.6.

[72] U.S. Census Bureau Data, "U.S. Corn Exports to Mexico 2022-Jan. 2024" (Exhibit USA-229).

## III. THE SPS CHAPTER OF THE USMCA APPLIES TO THE SUBSTITUTION INSTRUCTION JUST AS IT DOES TO THE TORTILLA CORN BAN.

53. As the United States demonstrated in its Initial Submission, both the Tortilla Corn Ban and the Substitution Instruction properly fall under Chapter 9 of the USMCA, as both measures constitute SPS measures and may, directly or indirectly, affect international trade.[73]

54. Mexico does not contest that the obligations in the SPS Chapter apply to the Tortilla Corn Ban.[74]

55. However, Mexico argues that the SPS Chapter does not discipline the Substitution Instruction because this measure has not been "applied."[75] Mexico further argues that, even if the Substitution Instruction is an SPS measure, it must be assessed as a provisional measure under USMCA Articles 9.6.4(c) and 9.6.5.[76]

56. In both cases, Mexico errs. As explained below, the Substitution Instruction has been adopted into law and contains a clear dictate to displace GE corn for certain uses with non-GE corn. The fact that it does not prescribe an exact timeline for that displacement does not render it inapplicable, nor does it make it provisional. Furthermore, it clearly "may, directly or indirectly, affect trade" in its current form and without further elaboration.[77]

### A. Mexico Errs in Arguing that the Substitution Instruction is not an SPS Measure Because It Has Not Yet Been "Applied."

57. Annex A, paragraph 1 of the SPS Agreement, incorporated by reference into the USMCA, defines an SPS measure as "[a]ny measure applied" to protect human, animal, or plant life or health as outlined in the Annex.[78] Mexico contends that the Substitution Instruction has not been "applied," and thus is not an SPS measure, because the Mexican government has not yet

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[73] *See* USMCA, art. 9.2; U.S. Initial Submission, Section V.B.

[74] *See* Mexico's Initial Submission, para. 323. The fact that Mexico asserts other purposes is irrelevant to whether the Tortilla Corn Ban constitutes an SPS measure. As the United States explained in its Initial Submission, and Mexico does not contest, past WTO panel reports have similarly explained that a measure that fulfills multiple purposes is nevertheless an SPS measure to the extent at least one of its purposes falls within the scope of Annex A, paragraph 1 of the SPS Agreement, incorporated by reference into the USMCA. *See, e.g.*, Panel Reports, *EC – Approval and Marketing of Biotech Products*, para. 7.166 (Exhibit USA-104).

[75] Mexico's Initial Submission, para. 308.

[76] *Id.*, para. 328.

[77] *See supra* Section II.C.

[78] *See* USMCA, art. 9.1.1.

fully defined or implemented the "appropriate actions" to execute the substitution of GE corn for use in animal food and industrial use for human consumption.[79] Mexico's argument is incorrect.

58. The Substitution Instruction unequivocally is an applied measure. The Substitution Instruction expressly states 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 consumption."[80] The Substitution Instruction mandates substitution. While the exact timing of when to take the "appropriate actions" is left to the discretion of the implementing agencies, whether or not to take the actions is not. This is a presidential decree with legal effect that provides an unambiguous instruction to substitute GE with non-GE corn for certain end uses. Should any relevant government agency in Mexico fail to comply with the provisions of the 2023 Corn Decree, including the Substitution Instruction, the Decree establishes that these agencies will be subject to administrative penalties.[81]

59. The fact that the Substitution Instruction does not delineate every detail as to how the agencies must carry out the provisions of this set of measures does not make it any less final. It is not uncommon for particular details of a law to become clear through further regulation or implementation. This possibility certainly does not cure USMCA inconsistencies that exist in the law itself, nor does it shield that law—again, here, a presidential decree that has been definitively adopted—from scrutiny. The Substitution Instruction does not include a future date for entry into force; it took effect on February 14, 2023, and remains in effect.[82] The Substitution Instruction constitutes an "applied" measure within the ambit of Annex A, paragraph 1 of the SPS Agreement.[83]

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[79] Mexico's Initial Submission, para. 307. Mexico further argues that the Substitution Instruction has not yet been "applied" because Mexico needs "more scientific evidence" to determine any risks from "industrially processed foods made from GM corn grain" and "animal products derived from livestock or fishes" raised with GE corn feed. *See* Mexico's Initial Submission, para. 331. As further explained in Section III.B, these alleged gaps, inexplicably directed at GE corn exclusively, are neither based on scientific principles nor rooted in reality, as safety assessments of GE plants and animal-derived commodities are routinely overseen by national regulators.

[80] 2023 Corn Decree, art. 7 (emphasis added) (Exhibit USA-3).

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

[82] *See id.*, First Transitory (providing that the Substitution Instruction "shall enter into force on the day following its publication in the Official Gazette of the Federation") (Exhibit USA-3).

[83] Furthermore, whether or not the Substitution Instruction has had a trade effect is not relevant to concluding if the measure constitutes an SPS measure within the definition of Annex A, paragraph 1, contrary to what Mexico argues. *See* Panel Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/R, para. 8.24 (adopted July 15, 2003) (Exhibit USA-230); *contra* Mexico's Initial Submission, para. 309 (stating that the Substitution Instruction is not an "applied" measure, as reflected in the alleged lack of trade effect on U.S. GE corn exports to Mexico).

### B. Mexico Errs in Arguing that the Substitution Instruction is a Provisional Measure.

60. Mexico further endeavors to avoid scrutiny of the Substitution Instruction by contending, in the alternative, that the Substitution Instruction is a "provisional" measure under USMCA Articles 9.6.4(c) and 9.6.5.[84] Mexico alleges that, whereas it has "clear scientific evidence" of the harmful effects on human health from consumption of dough and tortillas made of GE corn, Mexico needs "more scientific evidence" on GE corn in processed foods and animal products.[85] In other words, despite declaring in its Initial Submission that "[t]he human health risks arising from GM corn 'for animal feed and industrial use for human consumption' are similar in nature to those arising from GM corn grain for human consumption through nixtamalization or processing," Mexico nevertheless contends, without explanation, that it needs more evidence to determine any risks from GE corn in animal feed and industrial use for human consumption, as relevant to the Substitution Instruction.[86]

61. First, the Substitution Instruction is plainly not "provisional." The word "provisional," as relevant here, means "a temporary provision or arrangement; provided or adopted for the time being."[87] The text of the Substitution Instruction is not time limited, nor does it contemplate final adoption or replacement at some future date. Rather, it is a final, adopted measure currently in effect.

62. Having failed to adopt this measure consistent with the SPS disciplines underpinning the United States' claims, Mexico now resorts as a litigation tactic to characterize this final measure as "provisional" in nature. But this attempt is in vain, as USMCA sets several conditions for the legitimate adoption of a provisional measure under Articles 9.6.4(c) and 9.6.5 of the USMCA—conditions that were not met here.

63. To begin, a provisional measure is only permissible under Chapter 9 of the USMCA where the scientific evidence is "insufficient."[88] However, insufficiency of evidence is not an issue here.

64. As WTO dispute settlement reports have found in the context of Article 5.7 of the SPS Agreement, which contains similar language, an insufficiency of evidence should not be

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[84] Mexico's Initial Submission, para. 360; *see also* USMCA, art. 9.6.4(c) (providing that the SPS Chapter does not prevent a party from "adopting or maintaining a sanitary or phytosanitary measure on a provisional basis if relevant scientific evidence is insufficient").

[85] Mexico's Initial Submission, para. 358.

[86] *See id.*, paras. 330-331.

[87] "Provisional," *Oxford English Dictionary*, https://www.oed.com/dictionary/provisional_adj?tab=meaning_and_use#28008898 (Exhibit USA-231).

[88] *See* USMCA, art. 9.6.4(c).

conflated with scientific "uncertainty."[89] To impose a provisional measure, the existing scientific evidence must have deficiencies that inhibit a Party's ability to perform an adequate, objective risk assessment. However, such evidentiary limitations are not present here, as safety assessments of GE plants and animal-derived commodities are routinely overseen by national regulators, including in Mexico.

65. The *ex post* nature of Mexico's "provisional" argument is revealed by the measure's design. Had Mexico genuinely considered the scientific evidence around industrially processed foods to be insufficient, there would have been no reason to single out industrially processed foods made from GE corn as distinct from industrially processed foods made from non-GE corn grain. There is no scientific basis to assume that the former is less safe than the latter. If the raw agricultural commodity is as safe as its conventional counterpart, as Mexico's own regulators have determined (just like regulators around the world), then there is no reason to assume that processed products using GE corn present a unique risk as compared to processed products using non-GE corn. Therefore, Mexico has not shown why the current state of science does not allow Mexico to conduct a relevant risk assessment.[90]

66. Mexico's argument that it cannot currently assess food products derived from GE corn-fed animals is similarly meritless. The United States, Canada, and the European Union, among other countries, have been evaluating these same animal products for decades. The safety assessment of livestock commodities that consume GE plants is similar to the safety assessment of human foods derived from the same plants, adapted to take into account different animal species, life stages, exposure, consumption of different plant parts and byproducts than humans, and consideration of whether any new substances present in the animal-derived commodity are likely to accrue in the edible tissues of the animal.[91] This approach to the safety assessment of animal-derived commodities is generally consistent with that outlined in the Codex Guidelines, but adapted as appropriate for animals.[92] In fact, Mexico has traditionally assessed and

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[89] Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, paras. 183-184 (adopted Dec. 10, 2003) (Exhibit USA-232).

[90] To the extent Mexico focuses on glyphosate residues in processed corn products—even though Mexico does not discuss glyphosate in this section—studies have already determined that glyphosate residues do not concentrate in processed corn commodities. *See, e.g.*, EPA, "Glyphosate. Section 3 Registration for Application of the Potassium Salt of Glyphosate to Roundup Ready® Field Corn. Summary of Analytical Chemistry and Residue Data," at 4, 10 (Mar. 24, 2011) (Exhibit USA-233).

[91] In most cases, the newly expressed substances are the same as or similar to proteins or fats that are already present in animal food at comparable levels. These substances break down in the animals' gastrointestinal tracts into component amino acids or fatty acids, respectively, and are metabolized as other amino acids or fatty acids, and therefore do not accumulate in animal tissues.

[92] If, instead, Mexico is contending that its concern is actually animals that have been exposed to *glyphosate residue* (notwithstanding Mexico does not state such in its Initial Submission—*see, e.g.*, Mexico's Initial Submission, paras. 331, 345, 358-359, 455, which only refer to animal products fed with *GM corn*), then Mexico has not demonstrated (i) any scientific basis to only target GE corn and not also non-GE corn or other types of animal feed that may be

authorized GE corn events for use in animal feed, as well as for human consumption, so Mexico's suggestion that it does not have sufficient information to assess the safety of animal feed is belied by the very authorizations it has issued.[93]

67. In any event, to be consistent with its obligations regarding provisional measures, Mexico would need to, *inter alia*, "seek to obtain the additional information necessary for a more objective assessment of risk," complete the risk assessment, and review the provisional measure in light of the risk assessment.[94] In the year that has elapsed since the 2023 Corn Decree was issued, Mexico does not even attempt to demonstrate that it has undertaken any of these obligations.[95] For these additional reasons, the Substitution Instruction does not constitute a valid provisional measure.[96]

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treated with the pesticide; and (ii) why maximum residue levels ("MRLs") of pesticides like those established by other international regulators for animal foodstuffs are inadequate. *See* EPA, "R.E.D. Facts: Glyphosate" (Sept. 1993) ("The nature of glyphosate residue in plants and animals is adequately understood. . . . In animals, most glyphosate is eliminated in urine and feces. Enforcement methods are available to detect residues of glyphosate and AMPA in or on plant commodities, in water and in animal commodities.") (Exhibit USA-234); Codex Alimentarius, "Glyphosate – Pesticides Database Search" (including MRLs for animal-derived commodities) (Exhibit USA-235); European Commission, "Glyphosate – Pesticide Residue(s) and Maximum Residue Levels (mg/kg)" (including MRLs for animal-derived commodities) (Exhibit USA-236); EPA, 40 C.F.R. 180.364, "Glyphosate; tolerances for residues" (including MRLs for animal-derived commodities) (Exhibit USA-237).

[93] *See, e.g.*, [redacted]

[94] *See* USMCA, art. 9.6.5.

[95] *See* Mexico's Initial Submission, para. 359 (simply asserting that Mexico has sought to obtain additional information and claiming that the risk assessment requirement is "not applicable" "[a]t this stage").

[96] Mexico invokes the "precautionary principle" to further justify the Substitution Instruction as a provisional measure, but acknowledges that WTO reports have found that the precautionary principle "has not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement." *Id.*, paras. 355-356 n.389 (quoting Appellate Body Report, *EC - Hormones*, para. 124). The Panel's terms of reference here are to examine the matter at issue "in light of the relevant provisions of this Agreement [*i.e.*, the USMCA]." USMCA, art. 31.7. The "precautionary principle" is not referenced in Chapter 9 of the USMCA (and in any event has no single, agreed formulation in the international community).

# IV. MEXICO'S LEGAL ARGUMENTS REINFORCE THAT THE MEASURES AT ISSUE ARE NOT SCIENCE- OR RISK-BASED, CONTRARY TO THE SPS CHAPTER OF THE USMCA.

68. As the United States established in its Initial Submission, both the Tortilla Corn Ban and the Substitution Instruction are inconsistent with several provisions of the SPS Chapter of the USMCA.

69. In Section IV.A, *infra*, the United States demonstrates that Mexico has failed to rebut the U.S. claim that the Tortilla Corn Ban and the Substitution Instruction, respectively, breach Article. 9.6.3 of the USMCA, because neither was based on the relevant international standards or a risk assessment.

70. In Section IV.B, the United States demonstrates that Mexico has failed to rebut the U.S. claim that Mexico has contravened Article 9.6.6(a) of the USMCA, because the Tortilla Corn Ban and the Substitution Instruction, respectively, are applied beyond the extent necessary to achieve Mexico's alleged SPS objectives.

71. In Section IV.C, the United States demonstrates that Mexico has failed to rebut the U.S. claim that both disputed measures are not based on relevant scientific principles and therefore are inconsistent with Article 9.6.6(b) of the USMCA.

72. In Section IV.D, the United States demonstrates that Mexico has failed to rebut the U.S. claim that Mexico is in breach of Article 9.6.7 of the USMCA, because Mexico has no documented risk assessment or risk management for either the Tortilla Corn Ban or the Substitution Instruction, and did not afford other parties the opportunity to comment on any such documents.

73. In Section IV.E, the United States demonstrates that Mexico has failed to rebut the U.S. claim that Mexico did not take into account relevant international standards or available relevant scientific evidence when adopting the Tortilla Corn Ban and the Substitution Instruction, respectively, such that each measure is inconsistent with Article 9.6.8 of the USMCA.

74. Finally, in Section IV.F, the United States demonstrates that Mexico has failed to rebut the U.S. claim that the Tortilla Corn Ban and the Substitution Instruction, respectively, are more trade-restrictive than required to achieve Mexico's alleged ALOPs for human, animal, or plant life or health and thus each measure breaches Article 9.6.10 of the USMCA.

## A. Mexico Has Not Based its Tortilla Corn Ban or Substitution Instruction on Relevant International Standards or on a Risk Assessment as Required under Article 9.6.3 of the USMCA.

75. Mexico was required under Article 9.6.3 of the USMCA to base the Tortilla Corn Ban and the Substitution Instruction on relevant international standards, guidelines, or recommendations, provided that the relevant instruments exist and meet Mexico's ALOP. If

there are (i) no relevant international standards or (ii) relevant standards do exist but are not suitable to meet a Party's ALOP, then a Party nevertheless must base its measures on an appropriate risk assessment.[97]

76. In its Initial Submission, Mexico, for the first time, identifies the ALOPs that it asserts the Tortilla Corn Ban and Substitution Instruction are intended to satisfy. For the Tortilla Corn Ban, Mexico identifies a "zero risk" ALOP "to address risks from direct consumption of GM corn grain in dough nixtamalized, tortillas and related foods"[98] and some undefined "lower ALOP for the purpose of protecting native corn."[99] For the Substitution Instruction, Mexico claims an undefined "more 'risk tolerant'" ALOP for GE corn in animal feed and industrial use for human consumption and again an undefined "lower ALOP" for protecting native corn.[100]

77. In addition, Mexico summarily dismisses, without explanation, the relevant Codex and International Plant Protection Convention ("IPPC") standards that the United States identified in its Initial Submission, notwithstanding these are the relevant standard-setting bodies for food safety and plant health, respectively, as recognized in the USMCA.[101] Mexico's only justification for rejecting these relevant standards is an unsubstantiated statement that these standards "do not address the ALOP that Mexico considers relevant and appropriate to address risks to its population and native biodiversity."[102]

78. As an initial matter, Mexico has not adequately defined its ALOPs. Even Mexico's most "specific" ALOP, concerning the Tortilla Corn Ban and human health, refers to generic "risks from direct consumption," which does not define with adequate specificity what the ALOP is protecting against.[103] The other ALOPs for plant health and the Substitution Instruction are even

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[97] *See* USMCA, art. 9.6.3.

[98] Mexico's Initial Submission, para. 363.

[99] *Id.*, para. 349.

[100] *Id.*, paras. 344, 347.

[101] *See* U.S. Initial Submission, Section V.C; *see also* USMCA, art. 9.1.2 (incorporating by reference the SPS Agreement's definition of "relevant international standards, guidelines, or recommendations").

[102] Mexico's Initial Submission, para. 363. The United States also observes that "risks to [a] population and native biodiversity" are much broader concepts than the risks "posed to the Mexican population by glyphosate and GM protein residues in food, or to native Mexican corn varieties by unintended gene transfers from GM corn." *Id.*

[103] *See, e.g.*, Mexico's Initial Submission, para. 340 (referring generically to "contaminants and toxins in GM corn grain, *such as* transgenic proteins and glyphosate" (emphasis added)); *id.*, paras. 363, 385 (referring generically to "risks from direct consumption"); *see also id.*, paras. 130-151 (alleging various human health issues related to GE corn, including "nutritional quality deficiencies," "horizontal gene transfer," and "unintended consequences at the epigenetic level"); *id.*, para. 174 (stating generically that "ingestion of residual glyphosate and other contaminants. . . represent[] a serious food safety risk"); *id.*, para. 320 (referring to the "food safety risk" of "glyphosate and GMO-associated proteins (i.e., the Cry family of insecticidal toxins and molecules in glyphosate-tolerant corn events that act as free radicals, promoting oxidative stress associated with various chronic and degenerative diseases)"); *see also*

more vague and thus inconsistent with Mexico's obligation to define these levels of protection, especially in order for another Party to adequately scrutinize the adopted SPS measures.[104] That Mexico has fallen so woefully short in describing supposed ALOPs in the context of this dispute, only underscores the implausibility that they served as the guiding objectives for shaping Mexico's adopted measures now challenged by the United States.

79. In order for the United States to have some opportunity to respond to Mexico's alleged risks related to GE corn, the United States, for purposes of this Rebuttal, will refer to two generic categories of human health risks that Mexico references in its Initial Submission in relation to GE corn: (i) transgenic proteins and (ii) glyphosate residues.[105] In addition to these two human health risks, Mexico alleges a plant life or health risk: "transgenic introgression from the propagation of GM corn plants in Mexico."[106]

80. The United States reiterates that the Codex and IPPC standards are the relevant international standards for these alleged risks. Furthermore, these standards are capable of addressing any ALOP, even if Mexico had fulfilled its obligation to define the relevant ALOPs, which it has not.[107] Mexico has not demonstrated why either the Codex standards or the IPPC

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Panel Report, *Australia – Measures Affecting the Importation of Apples from New Zealand*, WT/DS367/R, paras. 7.970-7.971 (adopted Dec. 17, 2010) (hereinafter "Panel Report, *Australia – Apples*") ("Members should not be allowed to hide behind a generically stated ALOP.") (Exhibit USA-121). Mexico also has not articulated what it means by "zero risk" as a scientific matter (*e.g.*, no identifiable risk or something else).

[104] 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).

[105] *See* Mexico's Initial Submission, paras. 319-322.

[106] *See* Mexico's Initial Submission, paras. 324-326.

[107] The United States further contends that the ALOP that Mexico seeks to establish with respect to the protection of native corn—and the purported risk—are not relevant to this dispute and not based on science. Mexico explains that its ALOP is based on the allegation that the "cultivation of GM corn seed represents the greatest source of risk to native corn." Mexico's Initial Submission, para. 348. As the United States explained in Section I, the challenged measures in this dispute concern GE corn authorized for importation and sale for food or feed uses, *not* for cultivation, and Mexico's own government agencies have found no evidence of unauthorized release of GE corn or any damage to the environment. *See infra* Section IV.A.3.c; Judicial Branch of the Federation of the United Mexican States, Final Judgment 321/2013-I, at 15-16 (Sept. 28, 2023) (English excerpt) (Exhibit USA-165). Mexico's arguments in the Initial Submission concerning the protection of native corn are neither relevant nor based on science.

standards are irrelevant standards, nor has Mexico demonstrated why these standards are incapable of addressing Mexico's designated ALOPs.[108]

81. Moreover, even in the absence of a relevant international standard, Mexico would have needed to base its measures on a risk assessment. Mexico does not dispute that it has not performed a risk assessment for the Substitution Instruction.[109] And the "risk assessment" for the Tortilla Corn Ban that Mexico has, for the first time, put forward in lieu of following international standards is also not a risk assessment as defined under the USMCA, as explained further below.

82. Finally, as the United States will conclude in this section, *even if* Mexico had performed some assessment of risks, the science would not support a finding of the human and plant health risks that Mexico has alleged with respect to GE corn for food and feed. Accordingly, the measures simply could not have been based on an appropriate risk assessment consistent with Article 9.6.3.

83. In sum, Mexico has not based either measure on the relevant international standards, guidelines, or recommendations in existence, or on an appropriate risk assessment. Therefore, both the Tortilla Corn Ban and the Substitution Instruction contravene Article 9.6.3 of the USMCA.

### 1. The Codex and IPPC Standards are Relevant to the Risks Mexico Seeks to Address and Would Fulfill Mexico's ALOPs.

84. The Codex and IPPC international standards are not only recognized expressly in the USMCA but also are capable of fulfilling any ALOP Mexico might be seeking to protect human and plant life or health. As a result, Mexico was required to have based the Tortilla Corn Ban and Substitution Instruction on these standards, and by its own admission, did not.

85. Mexico articulated in its Initial Submission that it considers "proteins produced through the unintended expression of modified genes in agricultural crops" to be potential "contaminants," within the meaning of the SPS Agreement and alleges human health concerns related to glyphosate "pesticide residues" on GE corn.[110] Paragraph 3(a) of Annex A of the SPS Agreement, incorporated into the USMCA, affirms that the Codex standards relating to "food

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[108] If Mexico's argument is that these international standards do not apply purely because Mexico has alleged multiple SPS objectives and thus multiple ALOPs, such reasoning is not a credible basis for disregarding the universe of relevant international standards, guidelines, or recommendations recognized under the USMCA.

[109] *See* Mexico's Initial Submission, para. 359 (confirming that Mexico has not yet completed a risk assessment).

[110] Mexico's Initial Submission, para. 322 (citing Panel Report, *EC — Approval and Marketing of Biotech Products*, para. 7.313).

additives, . . . pesticide residues, [and] contaminants," are the relevant international standards for foods derived from GE plants.

86. As the United States explained in its Initial Submission, there are two relevant Codex standards for assessing food safety of GE products: (i) the Codex Principles, which outline a risk analysis approach for the "safety and nutritional aspects of foods derived from modern biotechnology";[111] and (ii) the Codex Guidelines, which further elaborate on the food safety assessment process for foods derived from GE plants.[112] The United States maintains that the Codex standards, including the Codex Principles and Codex Guidelines, are relevant to assessing the human health risks that Mexico has alleged with respect to consumption of GE corn. Indeed, even COFEPRIS—the Mexican regulatory authority responsible for assessing the safety of GE events—has confirmed that Codex provides the relevant standards applicable to safety assessments of GE foods.[113]

87. For example, the Codex Guidelines explain that a food safety assessment for a GE product should include an assessment of possible toxicity, possible allergenicity, and a compositional analysis of the GE plant to assess its nutritional content relative to conventional counterparts, as well as potential accumulation of pesticide residues.[114] Furthermore, the Codex Guidelines expressly acknowledge that "[c]onsumption patterns will vary from country to country depending on the importance of the food in the diet(s) of a given population(s)," and therefore recommend "that consumption estimates [be] based on national or regional food consumption data when available."[115] The Codex Guidelines are the internationally accepted standard on which to base a safety assessment of foods derived from GE plants; the Food and Agriculture Organization of the United Nations ("FAO") operates an entire FAO GM Foods Platform that captures the countries and events that have been assessed globally pursuant to the Codex Guidelines.[116] The Codex Guidelines are a framework for conducting a dietary risk

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[111] *See* Codex Principles, sec. 1, para. 4 (Exhibit USA-113); *id.*, sec. 2, para. 7 (Exhibit USA-113).

[112] Codex Guidelines, sec. 1, para. 3; sec. 13, para. 18; sec. 5, para. 16 (Exhibit USA-114).

[113] FAO GM Foods Platform, Mexico – Country Profile (affirming that Mexico "follows the relevant Codex Guidelines or national/regional guidelines that are in line with the Codex Guidelines in conducting safety assessment of GM food") (last modified Oct. 19, 2023) (Exhibit USA-217).

[114] Codex Guidelines, sec. 1, para. 3 (Exhibit USA-114); *id.*, sec. 3, para. 18 (Exhibit USA-114); *id.*, secs. 4-5, paras. 22-59 ("Some recombinant-DNA plants may exhibit traits (e.g., herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. The safety assessment should take this potential for accumulation into account.") (Exhibit USA-114); Codex Principles, sec. 1, para. 3 ("[R]isk analysis has been used over a long period of time to address chemical hazards (e.g. residues of pesticides, contaminants, food additives and processing aids).") (Exhibit USA-113).

[115] Codex Guidelines, sec. 3, para. 16 (Exhibit USA-114).

[116] *See* FAO GM Foods Platform, "Welcome to the FAO GM Foods Platform" (last accessed Mar. 13, 2024) (Exhibit USA-201).

assessment—which Mexico did not follow; the Guidelines are not some inflexible directive that is ill-suited to specific country conditions, as Mexico suggests.

88. To the extent Mexico focuses on glyphosate residues—which may be found on either GE or non-GE corn—Mexico acknowledges in its Initial Submission that the Codex Committee on Pesticide Residues ("CCPR") "is the authority responsible for setting Maximum Residue Limits (MRL) for pesticide residues in specific foods or in groups of foods or feeds moving in international trade."[117] Codex has established MRLs for pesticide residues in food and feed products, as well as in animal-derived commodities (*e.g.*, meat, poultry). These MRLs are standards for the maximum allowable amount (in mg/kg or ppm) of pesticide residue in a specific commodity at (a) the point of entry into a country or (b) the point of entry into trade channels within a country.[118] Codex has established 4,844 MRLs for different combinations of pesticides and commodities, including maize (corn), maize fodder, and sweet corn.[119] These MRLs apply to both GE and conventional commodities, as the use of pesticides is not a practice exclusive to GE products, and, indeed, studies have shown that the use of GE crops can reduce the need for pesticides.[120]

89. In order to establish these MRLs, a risk assessment is first required. The World Health Organization ("WHO"), in collaboration with the FAO, is responsible for assessing the risks to humans from pesticide residues in or on food, and for recommending adequate protection measures. Risk assessments are conducted by an independent, international expert scientific group, the FAO/WHO Joint Meeting on Pesticide Residues ("JMPR"). These assessments are based on all data submitted for national registrations of pesticides worldwide, as well as all scientific studies published in peer-reviewed journals.[121] After assessing the level of risk, JMPR establishes limits for safe intake to ensure that the amount of pesticide residue to which people are exposed through eating food over their lifetime will not result in adverse health effects.[122] Codex and national government bodies use these acceptable daily intake levels to establish

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[117] *See* Mexico's Initial Submission, para. 420.

[118] Codex, "Codex Pesticides Residues in Food Online Database," https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/it/ (Exhibit USA-238).

[119] *Id*.

[120] *See, e.g.*, 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).

[121] WHO, "Pesticide Residues in Food," https://www.who.int/news-room/fact-sheets/detail/pesticide-residues-in-food (Exhibit USA-214).

[122] *Id.* (Exhibit USA-214). JMPR assesses if the MRL will sufficiently protect consumers by assessing dietary exposure and risk from short- and long-term intake of pesticide residues. These assessments take into account available residue data and cultural dietary information. *See* FAO, "Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed," at 123 (2016) (Exhibit USA-242).

MRLs for pesticide residues in or on food, and countries may adjust these levels based on domestic consumption patterns or other scientific considerations.[123]

90. Mexico traditionally recognized the Codex MRLs, and as recently as 2017 reiterated that Codex MRLs served as an applicable guide in establishing Mexico's own MRL values, which included MRLs for corn, soybeans, canola, and cotton seed, among other commodities.[124] The United States understands that Mexico also historically accepted the MRLs established by the relevant regulatory bodies of trading partners.[125]

91. However, under the Tortilla Corn Ban, Mexico bans the use of GE corn for dough and tortillas regardless of whether the relevant MRLs are exceeded and regardless of the particular attributes of the GE corn event. Likewise, because the Substitution Instruction directs agencies to gradually eliminate the use of GE corn for animal feed and industrial use for human consumption, Mexico is singling out GE corn (without scientific basis) and prohibiting its entry,

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[123] *See, e.g.*, WHO, "Pesticide Residues in Food," https://www.who.int/news-room/fact-sheets/detail/pesticide-residues-in-food (Exhibit USA-214); EPA, "Setting Tolerances for Pesticide Residues in Foods" (last updated May 11, 2023), https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods#scientific-study (Exhibit USA-83). Codex is comprised of 188 member countries and one member organization (the EU). Some member countries develop their own MRL regulatory systems whereas others completely or partially defer to Codex for their MRLs. Using glyphosate (the most commonly used herbicide) as an example, approximately 140 markets have established glyphosate MRLs for corn as a raw material. Foodchain ID Regulatory Limits Database, "Summary of Corn, grain tolerances/MRLs and Residue Definitions," https://bcglobal.bryantchristie.com/db#/pesticides/query (Exhibit USA-243). Of these, approximately half of these markets follow the Codex glyphosate MRL for corn as a raw material (5.0 ppm); the other half, either on their own or as members of a regional bloc (*e.g.*, the EU), have established a glyphosate MRL for corn pursuant to their own regulations. For those markets that have developed their glyphosate MRL through their own regulations, approximately one-third have adopted the same glyphosate MRL as Codex (including the United States, Australia, and Japan), and approximately two-thirds have adopted 1.0 ppm (*e.g.*, the EU). A small number of markets have adopted their own glyphosate MRLs for corn as a raw material that range from .01 ppm to 3.0 ppm. *Id.* (Exhibit USA-243). Accordingly, the MRL system has been the widely accepted method for facilitating the importation of food or feed that is safe for dietary consumption.

[124] *See* Official Standard of Mexico, NOM-082-SAG-FITO/SSA1-2017, arts. 7.2.1, 8.1 (Oct. 4, 2017), https://faolex.fao.org/docs/pdf/mex170706.pdf (Exhibit USA-244); COFEPRIS, "Search of Sanitary Registrations of Pesticides, Plant Nutrients and MRLs," http://siipris03.cofepris.gob.mx/Resoluciones/Consultas/ConWebRegPlaguicida.asp (searchable database of Mexico's pesticide MRLs for commodities, including corn) (Exhibit USA-245); *see also* EPA, "NAFTA Guidance on Data Requirements for Pesticide Import Tolerances: Questions & Answers," https://www.epa.gov/pesticide-tolerances/nafta-guidance-data-requirements-pesticide-import-tolerances-questions-answers (last updated Feb. 20, 2024) ("Mexico accepts Codex MRLs on commodities for domestic consumption.") (Exhibit USA-246).

[125] Organization for Economic Co-operation and Development, "Regulatory Governance in the Pesticide Sector in Mexico," at 64-66 (2021), https://doi.org/10.1787/99adfd61-en (USA-247); United States International Trade Commission, "Global Economic Impact of Missing and Low Pesticide Maximum Residue Levels, Vol. 1," at 100 n.294 (June 2020), https://www.usitc.gov/publications/332/pub5071.pdf (Exhibit USA-248).

irrespective of whether the corn exceeds the applicable MRL.[126] This approach directly contradicts the prevailing approach set out by Codex and followed by countries around the world, including Mexico historically, which is meant to *allow* importation and sale where MRLs are not exceeded. Mexico has effectively eliminated its own MRL for corn, at least with respect to GE corn, without offering any scientific justification for deviating from this international framework and imposing the resultant import bans.

92. Just as with its treatment of the Codex standards, Mexico quickly dismisses the relevance of the standards set by the IPPC on plant health, notwithstanding that the USMCA identifies the IPPC as the relevant standard-setting body. Mexico asserts that the measures at issue are intended to address risks to native corn "arising from transgenic introgression of GM corn plant 'pests' into the environment."[127] Mexico again has not explained—and cannot explain—how the IPPC standards, which outline the pest risk analysis process, including for organisms modified through modern biotechnology, are irrelevant or inadequate due to Mexico's purported ALOP.[128] As Mexico admits, it has not based its measures on the IPPC standards, which expressly state that import prohibitions should only be considered following a risk assessment and as a "measure of last resort."[129]

93. Mexico has not demonstrated why the Codex and IPPC standards are not relevant and, moreover, are incapable of meeting Mexico's ALOP. Therefore, Mexico was obliged to base its SPS measures on these international standards but, by its own admission, did not do so.

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[126] The Substitution Instruction's provision stating that "alternatives for the gradual substitution in the country of genetically modified corn for animal feed and industrial use for human consumption shall be carried out . . . in accordance with scientific principles and relevant international standards, guidelines or recommendations" has been rendered meaningless, as Mexico has rejected the relevance of international standards in this dispute. *See* 2023 Corn Decree, art. 8 (Exhibit USA-3).

[127] *See* SPS Agreement, Annex A, para. 3(c) (Exhibit USA-34); Mexico's Initial Submission, para. 24; *see also id.*, para. 326 (explaining that the Tortilla Corn Ban is "applied to protect 'native corn' from risks arising from the spread of 'pest' GM corn plants" and thus "falls within the definition of SPS measure in Annex A.1 (a)"); *id.*, para. 334 ("each of the measures also falls within the SPS definition to the extent that they are applied to protect native corn (i.e., from the spread of GM corn plant "pests" that are spread from GM corn kernels)").

[128] *See* U.S. Initial Submission, Section V.C.1.b.

[129] *See* 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 ("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") (Exhibit-103); Secretariat of the IPPC, *International Plant Protection Convention*, arts. VII.1-2 (1997), https://www.ippc.int/en/publications/131/ ("In 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.") (Exhibit USA-102).

2. Mexico's "Risk Assessment" Does Not Conform to the Definition Under the SPS Chapter.

94. Even if there were no relevant international standards to address the risks Mexico has alleged, or these standards could not meet Mexico's alleged ALOPs, Mexico would be obligated to base the Tortilla Corn Ban and the Substitution Instruction on a risk assessment appropriate to the circumstances.

95. Mexico does not dispute that its Substitution Instruction has no risk assessment on which this measure was based.[130] It instead relies on fallacious arguments that the Substitution Instruction escapes scrutiny under Article 9.6.3 because either it has not been applied or it is a provisional measure—arguments that the United States rebutted in Section III.

96. Mexico does attempt to argue that it based the Tortilla Corn Ban on a risk assessment. However, the "risk assessment" that Mexico has now identified in these proceedings does not, in any way, constitute a risk assessment pursuant to Annex A, paragraph 4 of the SPS Agreement, which is incorporated into the USMCA under Article 9.1.

97. Mexico's explanation of its "risk assessment" in its Initial Submission is both incoherent and inadequate. Mexico defines its "risk assessment" as the report entitled "Scientific Dossier on Glyphosate and GM Crops" (hereinafter referred to as the "CONAHCYT Dossier") which in turn is purportedly derived from a "scientific collection" on the National Biosafety Information System ("SNIB"), for which Mexico provides a link to a generic homepage that has nothing to do with GE corn or even glyphosate in particular.[131] Mexico adds that this SNIB collection, which it also calls a "risk assessment," is "still in the process of obtaining more information."[132] Mexico also cites a multitude of articles in its Factual Background and Legal Arguments that it asserts are part of its "risk assessment" but do not appear in the CONAHCYT Dossier and have little to do with human health risks from consuming GE corn or alleged glyphosate residues on GE corn.[133]

98. Instead of basing Mexico's measures on internationally accepted standards, which Mexico has disavowed, Mexico "has relied on existing scientific literature and studies to assess

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[130] *See* Mexico's Initial Submission, para. 359.

[131] *See, e.g.* Mexico's Initial Submission, para. 251 n.326. Even if the SNIB link provided a collection of scientific articles on the topic of GE corn and glyphosate, an amalgamation of articles would not constitute a scientific risk assessment consistent with international standards, guidelines, or recommendations.

[132] *Id.*, para. 27.

[133] *See, e.g., id.*, Sections VII.E.4 (listing articles allegedly part of the "risk assessment" but most of which do not appear in the CONAHCYT Dossier); *id.*, Section V.D.1.c (discussing glyphosate exposure through means other than dietary consumption, let alone dietary consumption of GE corn); *id.*, Section V.D.2.a (citing studies about glyphosate exposure through spraying and means other than dietary consumption, let alone GE corn consumption); *id.*, Section V.D.2.b.1 (same); *id.*, Section V.D.2.c (same).

the risks to human health from the consumption of corn flour made from glyphosate-treated GM corn and glyphosate-based herbicides."[134] Contrary to what Mexico asserts, the CONAHCYT Dossier is not a risk assessment of potential risks to human health due to consumption of GE corn. Instead, the CONAHCYT Dossier is a high-level summary of miscellaneous topics ranging from the use of glyphosate globally; the number of permits and authorizations granted by the Mexican government, by commodity; exposure to glyphosate through means other than dietary consumption; and recommendations for weed management as an alternative to glyphosate.[135] Despite its assertion, Mexico has failed to adduce "clear scientific evidence" of the harmful effects of consuming GE corn in dough and tortillas.[136] To the contrary, Mexico's cited risk assessment (the CONAHCYT Dossier) contains one article alleging the presence of transgenes or glyphosate residues in a sample of tortillas and other corn products, which makes no assessment of dietary exposure or associated risk.[137]

99. The CONAHCYT Dossier does not come remotely close to a scientific risk assessment, nor does citing to an undefined database or a variety of articles. As Mexico acknowledges, Annex A, paragraph 4 of the SPS Agreement provides that a "risk assessment," in the context of food safety, must evaluate "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."[138] Dietary risk is a function of two elements: (1) **hazard** ("the potential for adverse effects on human health" or, in other words, how toxic a chemical is) and (2) **exposure** ("arising from the presence of contaminants in food . . . or feedstuffs").[139] However, Mexico has not assessed either element so as to meet its obligation under Article 9.6.3.

100. For context, international food safety standards and regulators typically break down these two elements—hazard and exposure—into a four-step process: (1) Hazard Identification; (2) Hazard Characterization; (3) Exposure Assessment; and (4) Risk Characterization.[140] Mexico, at most, has performed Hazard Identification—meaning Mexico has identified a chemical or biological agent potentially capable of causing adverse health effects. Mexico has not performed Hazard Characterization, which requires a dose-response assessment that analyzes health problems at different exposures through dietary consumption. Mexico has not performed an

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[134] *Id.*, para. 422.

[135] *See* MEX-085.

[136] *See* Mexico's Initial Submission, paras. 331, 345.

[137] *See* MEX-085, at 7 (citing MEX-125); *see also* Annex I (reviewing MEX-125).

[138] Mexico's Initial Submission, para. 366.

[139] *See* SPS Agreement, Annex A, para. 4 (Exhibit USA-34).

[140] *See* Codex, "Working Principles for Risk Analysis for Food Safety for Application by Governments," at 5, 9 (2007) (Exhibit USA-211); *see also, e.g.*, EPA, "Conducting a Human Health Risk Assessment" (last updated June 22, 2022) (Exhibit USA-212); EFSA, "The Four Steps of Risk Assessment," https://multimedia.efsa.europa.eu/riskassessment/index.htm (USA-213).

Exposure Assessment (*i.e.*, how much of the agent people are actually exposed to from GE corn during a specific time period). Mexico also has not completed Risk Characterization, meaning the qualitative or quantitative estimation of the probability of occurrence and severity of known or potential adverse health effects from consuming GE corn.[141]

101. Mexico presents certain studies that assert exposure to glyphosate has occurred through various means (*e.g.*, spraying) but does not evaluate the exposure that is relevant here—*i.e.*, exposure from glyphosate residues on GE corn—or even whether any exposure is likely to occur at levels that can cause adverse human health effects. Mexico does not provide any information in its Initial Submission or the CONAHCYT Dossier on the toxicological reference values (*i.e.*, the highest concentrations at which no adverse effects are observed, inclusive of any safety or uncertainty factors) that Mexico considers to be relevant for glyphosate.[142] Instead, Mexico presumes, without any assessment, that any level of exposure through dietary consumption constitutes a safety risk. Mexico does not provide any estimates of hazard, exposure, or risk from consuming GE corn treated with glyphosate—that is to say, the key pieces of a risk assessment, as defined under the USMCA, are entirely lacking. Similarly, the CONAHCYT Dossier and Initial Submission contain no assessment of any of the other alleged adverse effects from eating GE corn that Mexico has raised (such as *Bt* toxins and Cry proteins).

102. When evaluating a similar provision under the SPS Agreement (Article 5.1), past WTO dispute settlement reports have found that merely highlighting studies that show a general risk of disease or other adverse effects is not adequate to constitute a risk assessment—for example here, where a risk assessment reflecting the risks to human health resulting from dietary consumption of GE corn or foods derived from it is required.[143]

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[141] *Id.* (Exhibits USA-211, USA-212, USA-213).

[142] *See, e.g.*, FAO, "Human Health Risks – Dietary," https://www.fao.org/pesticide-registration-toolkit/registration-tools/registration-criteria/human-health-risks/dietary-risks/en/ (last accessed Mar. 24, 2024) (explaining how the acceptable daily intake is assessed by Codex, Australia, Canada, China, the EU, and the U.S., and how "[t]he principles and policies followed in the hazard assessment and end-point selection for dietary risks and the setting of toxicological reference values are similar across regulatory frameworks") (Exhibit USA-249). Typically these reference values include at least a 100x safety factor, to extrapolate data from experimental animal to the general population (interspecies differences), and from the general population to sensitive populations (intra-species differences). *Id.* (Exhibit USA-249). At a simplified level, regulators will evaluate laboratory animal toxicity studies that address a variety of different treatments, varying from acute (single) to chronic (long-term) exposures and identify any adverse effects that are relevant to humans. The regulators will then identify the acute or chronic exposure that is considered to be the greatest concentration at which no detectable adverse effects occur, and then reduce 100-fold to arrive at the chronic or acute reference value, out of an abundance of safety. *Id.* (Exhibit USA-249).

[143] *See, e.g.*, Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, para. 200 (adopted Feb. 13, 1998) ("The 1987 IARC Monographs and the articles and opinions of individual scientists submitted by the European Communities constitute general studies which do indeed show the existence of a general risk of cancer; but they do not focus on and do not address

103. Tellingly, Mexico's own judicial system has rejected past efforts by Mexico's regulatory agencies to categorically deny authorizations for GE corn events, predicated on a similarly generic list of studies and assertions about glyphosate and GE corn rather than a case-by-case assessment of risk. As the United States explained in its Initial Submission, for a period of three years—from May 2018 to August 2021—COFEPRIS halted new authorizations of GE events, notwithstanding the Biosafety Law's requirement to render a decision on an application within six months.[144] Starting in late 2021 through mid-2022, COFEPRIS rejected a spate of authorization applications for certain GE corn events, purely on the basis that these events contain a glyphosate-tolerant trait.[145] [redacted] Mexico, through the Tortilla Corn Ban and Substitution Instruction, is endeavoring to take these efforts even further by categorically banning all GE corn events—those already authorized and those that may be developed in the future, and irrespective of whether they have a glyphosate-tolerant trait—without so much as a risk assessment assessing human health risks arising from consumption of GE corn on a commodity or event-specific basis.

104. Mexico also defends its measures by reference to plant health (as distinct from human health), but it finds no more justification in a risk assessment in this regard. Annex A, paragraph 4 of the SPS Agreement, to which Mexico refers, provides that a plant health risk assessment should evaluate the likelihood of entry, establishment or spread of a pest or disease according to the SPS measures that might be applied, and the associated potential biological and economic consequences. However, Mexico has not even clearly defined what it understands the "pest" to be—at times referring to the "GM corn to be a pest" if it "grows in undesirable areas" and at other times referring to the "transgenic introgression" itself[147]—much less provided any level of specificity as to the traits or genes of concern.[148] The risk assessment that Mexico has proffered

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the particular kind of risk here at stake – the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes – as is required by paragraph 4 of Annex A of the *SPS Agreement*.") (Exhibit USA-250).

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

[145] *See* Government of Mexico, "Progress Report on the Compliance of the Decree About Glyphosate," at 35 (Nov. 11, 2022) (Exhibit USA-251); [redacted] (Exhibit USA-252).

[146] *See, e.g.*, [redacted]

[147] *See, e.g.*, Mexico's Initial Submission, paras. 24, 157, 324, 334.

[148] *See, e.g.*, Secretariat of the IPPC, *Pest Risk Analysis for Quarantine Pests*, sec. 2.1.1.1 (2017), https://www.ippc.int/static/media/files/publication/en/2017/05/ISPM_11_2013_En_2017-05-25_PostCPM12_InkAm.pdf ("In the case of [living modified organisms ("LMOs")], identification [of the pest]

does not explain in any form what actual or potential *harm* Mexico's native corn varieties are facing as a result of imported GE corn for use in dough and tortillas, or for industrial food use and feed.

105. Simply put, nothing in Mexico's Initial Submission, individually or collectively, would constitute a risk assessment under the USMCA.

3. *Even if* Mexico Had Conducted a "Risk Assessment," the Science Would Not Support the Presence of Risk.

106. To underscore how unmoored the disputed measures are from the relevant science, it is important to point out that *even if* Mexico had performed some "risk assessment," the disputed measures could not—as a logical or scientific matter—have been "based on" that assessment, because the issues Mexico has alleged in this dispute are not actual risks to human, animal, or plant life or health. In other words, *even if* the Panel were to find that Mexico has adequately defined its ALOPs, *and* the Panel finds that the Codex and IPPC international standards are not relevant or do not fulfill Mexico's ALOPs, *and* the Panel finds that Mexico performed some assessment of risk, the science would not support a finding of human health risk with respect to transgenic proteins and glyphosate residues present in or on GE corn, nor would the science support finding a risk to native corn from imported GE corn for food or feed. Consequently, the disputed measures could not have been "based on" an appropriate risk assessment.

107. Each alleged risk, and its lack of a scientific basis, is addressed in turn.

*a. GE Corn Does Not Contain Unsafe Levels of Glyphosate Residue.*

108. Mexico has provided no evidence that GE corn imported into Mexico presents unsafe levels of glyphosate residue.[149] The United States did not identify a single study, let alone a risk assessment, in Mexico's Initial Submission that evaluated adverse effects to human health from consuming GE corn with glyphosate residues, notwithstanding that is a risk that Mexico purports to be addressing through its measures.

109. Indeed, there is no indication that Mexico's concerns about glyphosate residues have any factual basis. Both the U.S. Department of Agriculture ("USDA") and the Food and Drug Administration ("FDA") maintain programs for ongoing monitoring of pesticide residues on both GE and non-GE crops and to support the EPA regulation of pesticide use in human food and

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requires information regarding characteristics of the recipient or parent organism, the donor organism, the genetic construct, the gene or transgene vector and the nature of the genetic modification.") (Exhibit USA-103); Secretariat of the IPPC, *Framework for Pest Risk Analysis*, sec. 1.2.4 (2007), https://www.ippc.int/static/media/files/publication/en/2016/01/ISPM_02_2007_En_2015-12-22_PostCPM10_InkAmReformatted.pdf (same) (Exhibit USA-117).

[149] *See also* Annexes II-III (addressing Mexico's statements and exhibits concerning agrochemical usage on GE crops and alleged glyphosate exposure).

animal feed. USDA's Pesticide Data Program ("PDP") randomly samples a variety of domestic and imported foods and tests them for pesticide residues, with a strong emphasis on foods that are consumed by children. PDP provides thousands of data points for each chemical on each crop, and typically tests commodities over a two-year period. Samples are taken at terminal markets or warehouses, just prior to foods being taken to grocery stores.[150] PDP uses analytical methods with very low limits of detection in order to detect residues at extremely low levels, well below established MRLs. In the latest PDP data available, from 2022, only one-fourth of all corn that USDA's PDP sampled had *any* detectable glyphosate residue at all, and, for those samples that did, the residue levels were a mere *one-twentieth to one-eighth of Mexico's domestic maximum residue level* of 1.0 ppm for glyphosate residue on corn (and well below the U.S. MRL of 5.0 ppm).[151] None of the samples came anywhere close to, let alone exceeded, Mexico's existing MRL for glyphosate residue on raw corn.

110. As further discussed above, the United States and countries around the world establish commodity-specific tolerance levels of pesticide residues in or on food, based on dietary risk assessments, to enforce safety of the global food supply. Mexico's unsubstantiated allegations of harmful glyphosate exposure from consuming GE corn are clearly not based on a risk assessment and are entirely meritless.

*b. Transgenic Proteins and Other Features of GE Corn Do Not Present a Human Health Risk, Contrary to Mexico's Assertions.*

111. In an effort to establish a human health risk, Mexico makes a multitude of allegations about the adverse effects of transgenic proteins and other human health "issues" as a result of consuming GE corn.[152]

112. Had Mexico performed an actual risk assessment, these allegations would have been rendered unsubstantiated, as the United States summarized in Section II.A and Annex I. For example, Mexico alleges "horizontal transfer of antibiotic resistance transgenes" but did not cite a single study showing stable integration of ingested DNA into the DNA of the organism

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[150] Samples are prepared emulating consumer practices—for example, washing or peeling. *See* USDA AMS, PESTICIDE DATA PROGRAM, ANNUAL SUMMARY, CALENDAR YEAR 2022, at 1 (Jan. 2024), https://www.ams.usda.gov/sites/default/files/media/2022PDPAnnualSummary.pdf (Exhibit USA-254).

[151] *See id.*, Appendix C (Exhibit USA-254); COFEPRIS, "Search of Sanitary Registrations of Pesticides, Plant Nutrients and MRLs," http://siipris03.cofepris.gob.mx/Resoluciones/Consultas/ConWebRegPlaguicida.asp (Exhibit USA-245). The sampling used an analytical method with a limit of detection of 0.035 ppm. Moreover, in the United States, compliance with the MRL for glyphosate residues in corn is determined by measuring glyphosate and N-acetyl glyphosate (a metabolite of glyphosate), whereas Mexico's residue definition is for glyphosate only. *See* Foodchain ID Regulatory Limits Database, "Summary of Codex, Mexico, U.S. Corn, grain tolerances/MRLs and Residue Definitions," https://bcglobal.bryantchristie.com/db#/pesticides/query (accessed Mar. 13, 2024) (Exhibit USA-255).

[152] *See* Mexico's Initial Submission, paras. 130-151.

consuming it. As a result, Mexico simply could not have performed an appropriate risk assessment on which to base its measures. Moreover, this theoretical risk is not unique to GE plants but applies to all DNA in food that is consumed by humans—from meat, to plants, to bacteria. However, the presence of DNA in food has not historically been a safety concern and is consumed every day in most meals.[153]

113. Notably, antibiotic resistance genes naturally exist in nature, typically in bacteria.[154] Only select few antibiotic resistance genes are (or were) used in GE plants; these antibiotic resistance markers are just "selection markers," which are tools developers use in the process of developing the transgenic crop, and are not intended to confer resistance to antibiotics. Careful consideration has gone into deciding which genes would be appropriate for use,[155] and the Codex Guidelines (which Mexico summarily rejects as irrelevant, without explanation[156]) have a section focused on the safety of such antibiotic resistance genes in food from GE plants.[157]

114. Like the various other allegations that Mexico asserted without support, exposure to transgenic proteins and DNA from consuming commercialized GE corn is not a legitimate food safety risk, as COFEPRIS's own safety assessments have confirmed.

### *c. GE Corn Imported for Food or Feed Use Has Not Harmed Native Corn Varieties, and Mexican Government Authorities Agree.*

115. Finally, Mexico claims that one of its objectives with the Tortilla Corn Ban and the Substitution Instruction is to protect native corn varieties from alleged transgenic introgression

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[153] Almost all foods, except those that are highly processed like vegetable oils, contain DNA. For example, the U.S. Food and Drug Administration has determined that DNA is "Generally Recognized as Safe" ("GRAS"). *See, e.g.*, U.S. Food & Drug Administration ("FDA"), "Statement of Policy – Foods Derived from New Plant Varieties" (May 1992), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statement-policy-foods-derived-new-plant-varieties (Exhibit USA-206).

[154] Rather than spreading from plant to bacteria, such genes are more likely to spread from bacteria to bacteria. Consequently, the likelihood that an antibiotic resistance gene would spread from a plant to bacteria would result in only a minimal increase spread of the gene compared to bacteria to bacteria spread.

[155] *See, e.g.*, FDA, "Secondary Direct Food Additives Permitted in Food for Human Consumption; Food Additives Permitted in Feed and Drinking Water of Animals; Aminoglycoside 3'- Phosphotransferase II," 59 Fed. Reg. 26,700 (May 23, 1994) (providing for the safe use of aminoglycoside 3'- phosphotransferase II (APH(3')II)—an antibiotic resistance marker—as a processing aid in the development of new varieties of tomato, oilseed rape, and cotton) (Exhibit USA-207).

[156] *See* Mexico's Initial Submission, paras. 361-362.

[157] Codex Guidelines, sec. 5, paras. 55-58 (Exhibit USA-114). *Even if* incorporation of antibiotic resistance genes would be adverse to human health, Mexico does not acknowledge the very low likelihood that this would occur or the fact that there may already be bacteria in the human gut containing these genes due to the natural presence of these genes.

(or "transgene flow") between GE corn and native varieties.[158] However, Mexico's arguments have no credibility as a factual matter. That is to say, even if Mexico had conducted a risk assessment, the science would not support that imported GE corn, intended for food or feed use, presents a risk to the life or health of native corn. Mexico's own government agencies have stated the same before a Mexican court of law.

116. In Mexico's Initial Submission, Mexico refers to a collective action in 2013 that resulted in a preliminary injunction on cultivation of GE corn seeds in Mexico.[159] Mexico claims—without pointing to any risk assessment—that even this injunction (concerning cultivation) is not enough to protect native corn and thus a ban on GE corn imports for food and feed is the only path forward.

117. However, what Mexico does not acknowledge is that, after 10 years of the injunction, the Mexican court system finally heard the merits of the case last year and resoundingly aligned with the defense, finding the allegations that permit holders were illegally releasing GE corn into the environment and causing harm to Mexico's native corn varieties as completely "unfounded."[160]

118. As the court firmly concluded:[161]

> [T]here is no evidence in the proceedings that the introduction of genetically modified corn, not allowed as referred to by the plaintiff, has taken place. Likewise, the damage to the biological diversity of native corn is not proven with suitable evidence, nor is the violation of any human right, as well as the existence of any present and real damage to the plaintiff collective to the detriment of the diffuse rights protected by the Political Constitution of the United Mexican States, International Treaties, and applicable legal norms to regulate the release into the environment of genetically modified corn in its experimental, pilot and commercial phases, such as the Law of Biosecurity of Genetically Modified Organisms and its Regulation, specifically the Twelfth Title called *"Special Protection Regime for Corn,"* as well as the Agreement whereby Centers of Origin and Centers of Genetic Diversity of Corn are determined.

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[158] Mexico's Initial Submission, para. 24. Mexico claims that "the cultivation of GM corn seed represents the greatest source of risk to native corn,"[158] notwithstanding that argument is irrelevant to the Substitution Instruction and Tortilla Corn Ban, which concern GE corn intended only for food and feed.

[159] Mexico's Initial Submission, Section V.E.4 ("Legal proceedings against the planting of GM corn in Mexico").

[160] Judicial Branch of the Federation of the United Mexican States, Final Judgment 321/2013-I, at 3 (Sept. 28, 2023) (English excerpt) (Exhibit USA-165). Mexico also does not acknowledge that this collective action was led by a class representative who now serves in the Mexican Government as the Director General of the Primary Sector and Renewable Natural Resources at the Secretariat of Environment and Natural Resources ("SEMARNAT").

[161] *Id.* at 3-4 (Exhibit USA-165).

119. Mexico's own government agencies, including [redacted], participated in the proceedings and dismissed the allegations of the collective:[163]

> [redacted], when appearing in this trial . . . expressly stated that, . . . in relation to the presence of the release of transgenic corn in unauthorized places, [it] does not have information, data or indications that such activity is actually being carried out in any unauthorized part of the country.

120. In addition to [redacted], Mexico's Federal Economic Competition Commission, Secretariat of Health ("SALUD"), Federal Prosecutor's Office for Environmental Protection, Secretariat of Finance and Public Credit ("SHCP"), Inter-Secretarial Commission on Biosafety of Genetically Modified Organisms ("CIBIOGEM"), and National Council of Science and Technology ("CONAHCYT") all stated that "they have *no knowledge of the existence of the acts referred to by the plaintiff in their complaint or of the existence of any damage to the environment, or to any other fundamental right, due to the release of genetically modified corn into the environment*."[164]

121. The court further found that accidental or involuntary release "was not proven in any way at trial," and even if such releases had occurred, that "does not mean that there is an impairment or damage to the biological diversity of native corn," observing that there are remediation procedures under the Biosafety Law to regulate and sanction unauthorized behavior.[165] The court went even further to state that, *even if* there were no remediation procedures available under Mexico's Biosafety Law:[166]

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[162] [redacted]

[163] *Id.* at 4-5 ("Thus, it is possible to conclude that the plaintiff's assertions are unfounded, and therefore, the damage or impairment of any human right derived from alleged facts that do not exist, nor have been carried out, as expressly stated and affirmed in this proceeding by the Federal Prosecutor's Office for Environmental Protection, the competent authority and empowered to determine the existence of such facts, and consequently, the benefits claimed by the plaintiff collective are unfounded.") (Exhibit USA-165).

[164] *Id.* at 16 (emphasis added) ("Furthermore, the reports show that the Mexican State has recognized the benefits of biotechnology to satisfy the food needs of the population and the effective care of the environment . . . .") (Exhibit USA-165); *id.* at 17 (further finding that "the plaintiff did not provide a technical scientific report or any other suitable means of conviction, by which it could accredit what it asserts" and "the defendants accredited with suitable means of proof their arguments of defense, which lead this federal authority to declare the action initiated by the plaintiff collective unfounded") (Exhibit USA-165).

[165] *Id.* at 5 (Exhibit USA-165).

[166] *Id.* at 5-6 ("Also in this Global Native Corn Project, the biological diversity of native corn in the national territory is guaranteed, as a great diversity of originally registered native breeds has been found, and the in situ and ex situ

> [T]his does not imply in any way that the accidental or involuntary release of genetically modified corn, if any, necessarily entails the extinction of native corn, or that it irreparably affects the biological diversity of such native corn, since its conservation is fully guaranteed both in situ (environment) and ex situ (germplasm banks); this was accredited in the proceedings with the [redacted], conducted by the National Commission for the Knowledge and Use of Biodiversity, in which it was concluded that the conservation both in situ and ex situ of the diversity of native corn is fully guaranteed, and that to date there are even a greater number of breeds and varieties of them, which shows that the biological diversity of native corn has been growing, even in spite of the facts that the plaintiff narrates without any accreditation whatsoever. . . .

122. For avoidance of doubt, the court firmly rejected the collective's claims that use of GE corn grain could negatively impact Mexico's biodiversity and reaffirmed their ability to coexist, whether the GE corn grain were cultivated or imported for food and feed use:[167]

> [T]he use of genetically modified corn seeds in no way jeopardizes the utilization of native corn in a way and at a rate that causes a long-term decrease in biological diversity, nor does it imply in any way that the possibilities of satisfying the needs and aspirations of current and future generations are diminished, with respect to native corn, since the planting of genetically modified corn in no way affects the subsistence of native corn, since these can coexist simultaneously without the existence of one implying the extinction or reduction of the other. . . .
>
> It has been proven in court by the defendants that, through scientific research carried out by renowned scientists in the area of biotechnology, the release of genetically modified corn does not affect in any way the biological diversity of either native corn or other components of biodiversity.
>
> With respect to the diversity of native corn, it was demonstrated that it is guaranteed, and the plaintiff collective has not demonstrated that it has suffered any repercussions from the release of genetically modified corn into the environment, or from the authorization of

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conservation of the biological diversity of these corn varieties is fully guaranteed.") (Exhibit USA-165); *id.* at 6 ("The foregoing, added to the fact that native corns in our national territory have been produced and consumed in a constant and uninterrupted way, so that in no way is the sustainable use of native corns threatened, clearly defined in the Convention on Biological Diversity of 1992 . . . .") (Exhibit USA-165).

[167] *Id.* at 6-7 (court also acknowledging the very benefits of agricultural biotechnology that the United States outlined in its Initial Submission: "With regard to the conservation of the different components of biodiversity, it was proven in court that the use of biotechnology for corn cultivation facilitates the implementation of no-till and reduced tillage agriculture, which reduces the carbon footprint by reducing carbon dioxide emissions from agricultural equipment and soil erosion. Furthermore, the use of genetically modified corn implies higher agricultural productivity, drought tolerance, insect and disease resistance, which can also save valuable water resources, agricultural soil and reduce deforestation.") (Exhibit USA-165).

events of this type of corn for activities related to its importation, use or consumption. . . .

123. The court pointed out that Mexico's Secretariat of Agriculture and Rural Development ("SADER") historically issued upwards of 200 permits for the release into the environment of GE corn "without there being a single report or technical opinion from which it can be inferred that through the exercise and compliance with such permits there has been damage or affectation to the biological diversity of native corn, or to the sustainable use thereof, or the inadequate, fair and equitable participation in the benefits of the use of biotechnology."[168] As relevant to the challenged measures in this dispute, the court further acknowledged that, since 2002, COFEPRIS has evaluated and issued authorizations for GE corn events for use as food or feed (not for cultivation), and done so upon finding that these events are "not being toxic, and not representing a risk or danger for human, animal or plant health, and it has also granted the corresponding authorization by virtue of being substantially equivalent to its conventional counterpart."[169]

124. As a result, there is no evidence that imported GE corn authorized for food or feed purposes is negatively affecting Mexico's native corn varieties.[170] Indeed, there is not even evidence that GE corn seeds licensed for *release* (*i.e.*, cultivation) have ever had an adverse effect on the life or health of Mexico's native corn, as recently reaffirmed in Mexico's own court system.

125. Mexico in fact dedicates an entire section of its Initial Submission to a 2004 report by the Commission for Environmental Cooperation ("CEC"), which makes this very point.[171] The report, which hypothesizes—without basing any conclusions on scientific analysis—that the importation and unapproved planting of transgenic corn from the United States is the source of transgenes in Mexico's landraces, concedes that "[t]here is no reason to expect that a transgene

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[168] *Id.* at 7-8 (Exhibit USA-165).

[169] *Id.* at 7 (Exhibit USA-165).

[170] Instead, Mexico just makes vague allegations, such as, "Transgenes in GM corn can potentially generate negative genetic and physiological changes in conventional corn," citing nothing and avoiding any detail on what those "negative" changes are. *See* Mexico's Initial Submission, para. 122. Mexico further alleges that "[t]he presence of genetically modified sequences, derived from transgene flow or introgression (fixation) of transgenes, can potentially affect the physiological characteristics of native corn related to the proportion and amount of total proteins," citing MEX-098, but the cited source does not provide any evidence that alleged physiological changes negatively affect the plant. Presence of a transgene in a native variety is not evidence of any harm to the plant, even if there are measurable changes in proteins.

[171] *See* Mexico's Initial Submission, Section 5.C.3.

would have any greater or lesser effect on the genetic diversity of landraces or teosinte than other genes from similarly used modern cultivars."[172] The report goes on:[173]

> Transgenes are unlikely to displace more than a tiny fraction of the native gene pool, if any, because maize is an outcrossing plant with very high rates of genetic recombination. Instead, transgenes would be added to the dynamic mix of genes that are already present in landraces, including conventional genes from modern cultivars. Thus, the introgression of a few individual transgenes is unlikely to have any major biological effect on genetic diversity in maize landraces.

126. It is common knowledge that Mexico's present-day native corn varieties are a product of ongoing cross-breeding and evolution over millennia, including cross-breeding with non-native hybrids[174] and that Mexico's own policies have encouraged the use of hybrids (including for use in tortillas) over the use of native landraces.[175] Nevertheless, Mexico's 2023 Corn Decree does

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[172] *See* MEX-095, at 17.

[173] *Id.* at 17, 19 ("Scientific investigations and analyses over the past 25 years have shown that the process of transferring a gene from one organism to another does not pose any intrinsic threat over the short or long term, either to health, biodiversity or the environment . . . regardless of whether the new genes are transgenes or not."); *see also id.* Annex 3 (containing U.S. government comments on the report, noting that the report "ignores key science about biotechnology" and "many of the recommendations of the report are inconsistent with [the report's] own scientific findings that biotech maize and other modern maize hybrids behave similarly in the environment").

[174] *See, e.g.*, I. Rojas-Barrera et al., "Contemporary Evolution of Maize Landraces and Their Wild Relatives Influenced by Gene Flow with Modern Maize Varieties," 116 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES 21302 (Oct. 2019), https://www.pnas.org/doi/epdf/10.1073/pnas.1817664116 (assessing the adoption of non-GE hybrids and observing introgression (*i.e.*, gene flow) from hybrids into native landraces) (Exhibit USA-166).

[175] *See, e.g.*, "MasAgro Maize," *CIMMYT*, https://masagro.mx/descripcion-general/ (a project of Mexico's Secretariat of Agriculture and Rural Development and the International Maize and Wheat Improvement Center ("CIMMYT"), from 2010-2020, which promoted sustainable development through the breeding of maize hybrids with native seed) (Exhibit USA-167); F. D. McLean-Rodríguez et al., "The Abandonment of Maize Landraces Over the Last 50 Years in Morelos, Mexico: a Tracing Study Using a Multi-level Perspective," 36 AGRICULTURE & HUMAN VALUES 651, 653, 655-656 (2019), https://link.springer.com/article/10.1007/s10460-019-09932-3 ("Among the surveyed farmers, the adoption of hybrids was the principal cause for landrace abandonment . . . . In farmers' words, they preferred hybrids over landraces because of their higher yield by weight [and] . . . greater resistance to pests and diseases[.]") (Exhibit USA-168); *id.* at 661 ("[F]armers preferred hybrids because they found them to be more resistant to dry spells and drought than landraces," further explaining that hybrids were more marketable to and favored by tortilla manufacturers) (Exhibit USA-168); *id.* at 662 ("Farmers mentioned they became interested in hybrids after receiving financial subsidies or technological packages from government authorities," noting that "[a]s part of the national strategy for maize self-sufficiency, the Secretary of Agriculture has allocated resources to support hybrid adoption through state governments.") (Exhibit USA-168); *id.* at 664 ("In the municipalities the most common reason for landrace abandonment was the agronomic superiority of the hybrids. However, we found that the preference for hybrids was supported by an entire enabling environment that emerged through the combination of changes in the technological, market, policy and cultural regimes. This enabling environment favored the displacement of landraces by hybrids, other crops, and other economic activities, particularly during the shift from

not target these types of hybrid corn. Mexico's position, without basis, is that the mere presence of a gene harms plant life or health. Moreover, that harm can only occur where that gene comes from a GE corn crop; native corn crossbreeding with hybrids or teosinte (a non-corn species) is apparently acceptable, as they are not targeted by the Tortilla Corn Ban or the Substitution Instruction, notwithstanding that these measures are intended to protect native corn varieties, according to Mexico.

127. Even if Mexico could show that GE corn imports intended for food or feed have affected the genetic composition of Mexico's native corn varieties (notwithstanding its statements to the contrary before a court of law), the United States is not aware of any scientific evidence supporting that such activity would present a risk to plant life or health, and Mexico's government agencies have agreed.[176]

128. As the United States will explain further in the next section, Mexico's native corn justification for the measures at issue is not based on fact and is instead a contrived (and unavailing) pretext for these USMCA-inconsistent measures.

129. To summarize, Mexico has breached Article 9.6.3 of the USMCA for each of the following reasons: Mexico has not adequately defined its ALOPs; Mexico has not based its measures on the relevant international standards; and, in the alternative, Mexico has not conducted a risk assessment consistent with Annex A of the SPS Agreement. Furthermore, *even if* the Panel were to find that Mexico completed some risk assessment, Mexico could not have based the disputed measures on an appropriate risk assessment because the facts do not support the existence of such risks. As such, both the Tortilla Corn Ban and the Substitution Instruction breach Article 9.6.3 of the USMCA.

### B. Both the Tortilla Corn Ban and the Substitution Instruction Breach Article 9.6.6(a) Because Both are Applied Beyond the Extent Necessary to Achieve Mexico's Alleged SPS Objectives.

130. Neither Mexico's Tortilla Corn Ban nor its Substitution Instruction is applied "only to the extent necessary," as required under Article 9.6.6(a) of the USMCA. Indeed, neither measure actually serves any human, animal, or plant life or health objective and thus neither is necessary at all.

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one farmer generation to the next.") (Exhibit USA-168). This article was funded by Consortium of International Agricultural Research Centers ("CGIAR") Research Program on MAIZE Agrifood Systems through CIMMYT, which is funded in part by Mexico and the United States, as well as other donors. *See* "Our Funders," *CGIAR & CIMMYT*, https://www.cimmyt.org/about/funders/ (Exhibit USA-169).

[176] *See also infra* Section IV.B (further explaining how these measures do not serve a plant life or health purpose, as a scientific matter).

### 1. The Tortilla Corn Ban Does Not Address Any Human or Plant Health Risk and Thus Does Not Meet Article 9.6.6(a) of the USMCA.

131. Banning the importation and use of GE corn in dough and tortillas does not contribute to the human or plant health risks that Mexico alleges in its Initial Submission. Even if it did, Mexico would have less trade-restrictive measures available and that are better suited to address such concerns.

132. Referring to the Tortilla Corn Ban, Mexico asserts that, because its designated ALOP is "zero risk" with respect to protecting human health, Mexico can ban the importation of GE corn for use in dough and tortillas. Again, this measure is not based on international standards, guidelines, or recommendations, nor is it based on any risk assessment that would suggest that the GE corn events authorized for importation and sale in Mexico—as well as all those that may be developed in the future—for use other than cultivation are intrinsically hazardous to human health.[177]

133. Mexico looks to Articles 2.2 and 5.6 of the SPS Agreement and argues that the Tortilla Corn Ban is "not more trade-restrictive than required" to achieve Mexico's ALOP and thus can be deemed necessary, as the measure only reaches certain end uses.[178] Mexico further justifies its position by emphasizing that the majority of U.S. GE corn exports to Mexico are not for use in dough and tortillas. This argument misses the point. That the Tortilla Corn Ban does not reach the majority or all of U.S. exports of GE corn to Mexico does not prevent it from breaching Mexico's commitments. Rather, Article 9.6.6(a) of the USMCA requires that the measure be necessary to serve the designated purposes under Annex A, paragraph 1 of the SPS Agreement, and the Tortilla Corn Ban serves neither a human health nor plant health purpose.

134. Mexico has provided no evidence that GE corn imported into Mexico, including for use in dough and tortillas, presents unsafe levels of glyphosate residue or any other credible risk to human health.[179] However, if Mexico had a legitimate, scientifically supportable concern about the risk of glyphosate residue, it should have relied on current or modified MRLs, employed by Codex and countries around the world to ensure the safety of the global food supply. These MRLs would apply to both GE and non-GE corn, because glyphosate may be used on either type of corn. Moreover, the MRLs would apply to all corn intended for human consumption (*i.e.*, not just use in dough and tortillas). Instead, Mexico has implemented a measure that is not rooted in science and not "necessary" to protect human health.[180] The Tortilla Corn Ban is therefore

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[177] *Supra* Section IV.A.

[178] Mexico's Initial Submission, paras. 375, 385-386 (quoting SPS Agreement, art. 5.6).

[179] *See also* Annexes II-III (addressing Mexico's statements and exhibits concerning agrochemical usage on GE crops and alleged glyphosate exposure).

[180] Mexico also has not addressed why its prior safety assessments of commercialized GE events were incorrect in their food safety findings.

inconsistent with Article 9.6.6(a) of the USMCA.

135. Similarly, the Tortilla Corn Ban does not address any legitimate risk to Mexico's native corn varieties. Simply put, GE corn that is imported *for use in dough and tortillas* cannot feasibly affect native corn fields. As a scientific matter, GE corn grain that is imported, in and of itself, cannot cross-pollinate with a native corn variety. Rather, it would first need to be planted in the ground (which is banned in Mexico) and would need to sprout and grow to maturity; it takes two months before a corn plant develops sufficiently to the point where it can even release pollen.[181] Then, the pollen from the GE corn plant would need to travel from the tassel (the male flower) to the silk (stigma and style of the female flower) of the native corn plant.

136. However, corn pollen is relatively large and heavy, such that it falls to the ground rapidly in a limited area and typically does not travel far.[182] Therefore, even when GE corn and non-GE corn are intentionally cultivated in close proximity to one another, which is far from the situation of importing GE corn for dough and tortillas, studies have found that the vast majority of corn pollen falls within five meters of a field's edge,[183] and 98 percent of pollen travels no further than ten meters.[184]

137. On top of this, the likelihood of a GE plant cross-pollinating with a non-GE plant depends on a combination of factors that must align for cross-pollination to even occur. These factors include (i) the GE pollen must still be viable for fertilization; (ii) the timing of flowering of the non-GE crop must coincide with the GE crop; and (iii) the foreign pollen must compete with fresher pollen produced by the non-GE plant itself or pollen from any other non-GE plants in the vicinity.[185] Studies have found that cross-pollination levels are a mere one percent or less

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[181] Thus, to the extent that there were illegal or inadvertent cultivation of the GE corn grain, a farmer or other interested party would have a full two months to remove the sprouting plant before it would even produce any pollen. Corn is a highly domesticated plant, meaning that it depends on human assistance to survive. The United States is also not aware of any traits that have been introduced into GE corn that have increased the weediness of corn such that could persist in the environment without human assistance.

[182] *See* G. Brookes et al., "Genetically Modified Maize: Pollen Movement and Crop Co-existence," PG ECONOMICS, at 5, 16-17 (Nov. 26, 2004) (hereinafter "G. Brookes et al.") (Exhibit USA-170).

[183] *See, e.g.*, J. M. Pleasants et al., "Corn Pollen Deposition on Milkweeds In and Near Cornfields," 98 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES 11919 (2001) (Exhibit USA-256).

[184] F. Bénétrix & D. Bloc, "GMO and Non-GMO Maize Possible Coexistence," 294 PERSPECTIVES AGRICOLES 14 (Oct. 2003), https://www.perspectives-agricoles.com/sites/default/files/imported_files/294_2517614035949889030.pdf (further finding that a separation distance of 50 meters reduced pollen presence to 0.9 percent) (Exhibit USA-257).

[185] G. Brookes et al., at 4 (Exhibit USA-170); *see also* K. Zhang et al., "Pollen-Mediated Transgene Flow in Maize Grown in the Huang-huai-hai Region in China," 149 JOURNAL OF AGRICULTURAL SCIENCE 205, 206 (2011) (summarizing the factors that can influence transgene flow) (Exhibit USA-258). A corn plant may shed pollen for up to two weeks, but usually only does so for five to eight days, peaking around the third day. A given pollen grain is only viable for a period ranging from a few hours to one day. In turn, receptive silks on the receptor plant are

where GE crops and non-GE crops are grown at a distance of 30 meters.[186] Using buffer crops, isolation distances, barriers,[187] and variation in planting times can further lower the levels of cross-pollination and are commonly recognized "co-existence" measures.[188] Accordingly, the suggestion that GE corn imported for use in dough and tortillas threatens the well-being of native corn landraces defies scientific reason, and Mexico has provided no logical explanation based in science for how this would plausibly occur.

138. Even if Mexico could show that GE corn imports intended for use in dough and tortillas have affected the genetic composition of Mexico's native corn varieties, the United States is not aware of any scientific evidence supporting that such activity would present a risk to plant life or health.[189] Gene flow is a biological process wherein genes from one plant are transferred to

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viable for only approximately 10 days. *See, e.g.*, R. L. Nielson, "Silk Development and Emergence in Corn" (July 2020), https://www.agry.purdue.edu/ext/corn/news/timeless/Silks.html (Exhibit USA-259); G. Della Porta et al., "Maize Pollen Mediated Gene Flow in the Po Valley (Italy): Source-recipient Distance and Effect of Flowering Time," 28 EUROPEAN JOURNAL OF AGRONOMY 255, 256 (2008) (citing studies) (explaining that "silks are receptive for about 5 days and senesce within 8 days if not fertilized" (citation omitted)) (hereinafter "G. Della Porta et al.") (Exhibit USA-260).

[186] *See, e.g.*, G. Della Porta et al., at 255-256 (citing studies) (Exhibit USA-260); G. Brooks et al., at 7-8, 12-13 (same) (Exhibit USA-170); B. L. Ma et al., "Extent of Cross-Fertilization in Maize by Pollen from Neighboring Transgenic Hybrids," 44 CROP SCIENCE 1273 (2004) (finding the rate of cross-fertilization was less than 1 percent beyond 28 meters downwind and 10 meters upwind) (Exhibit USA-261); M. Palaudelmàs et al., "Sowing and Flowering Delays Can Be an Efficient Strategy to Improve Coexistence of Genetically Modified and Conventional Maize," 44 CROP SCIENCE 2404, 2405 (Nov. 2008) ("[I]t can be concluded that a separation distance of 20 to 25 m will generally be enough to maintain the GM content below the 0.9 percent threshold in the yield of neighboring fields of non-GM maize.") (hereinafter "M. Palaudelmàs et al.") (Exhibit USA-262); J. Messeguer et al., "Pollen-mediated Gene Flow in Maize in Real Situations of Coexistence," 4 PLANT BIOTECHNOLOGY JOURNAL 633 (2006) ("[I]n the case of a fully synchronous flowering time, a security distance between transgenic and conventional fields of about 20 m should be sufficient to maintain the adventitious presence of genetically modified organisms as a result of pollen flow below the 0.9 percent threshold in the total yield of the field.") (Exhibit USA-263).

[187] Objects such as hedges and trees, as well as topography, can affect levels of cross-pollination by interrupting and diverting airborne pollen flow. *See* G. Brooks et al., at 17 (Exhibit USA-170); *see also* B. M. Baltazar et al., "Pollen-Mediated Gene Flow in Maize: Implications for Isolation Requirements and Coexistence in Mexico, the Center of Origin of Maize," PLOS ONE, at 12 (July 10, 2015), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0131549 (hereinafter "B. M. Baltazar et al.") (Exhibit USA-264).

[188] G. Brooks et al., at 7, 13-18 (Exhibit USA-170); B. M. Baltazar et al., at 12-13 (Exhibit USA-264); G. Della Porta et al., at 255, 261 (finding close to zero percent cross-fertilization when offset flowering times by 7 days or more and identifying buffer maize plants that shed competitive pollen as most efficient barrier to cross-fertilization) (Exhibit USA-260); M. Palaudelmàs et al., at 2404, 2410-2412 (finding similar) (Exhibit USA-262); Y. Devos et al., "The Co-existence Between Transgenic and Non-transgenic Maize in the European Union: A Focus on Pollen Flow and Cross-Fertilization," 4 ENVIRONMENTAL BIOSAFETY RESEARCH 71, 77-84 (2005) (Exhibit USA-265).

[189] *See, e.g.*, Biotechnology Committee of the Mexican Academy of Sciences, at 350-351 ("By means of amparos [constitutional protections] and lawsuits – some of them filed before the judiciary – certain opposition and very

another genetically distinct plant through pollen flow. If a transgene is exchanged between plants, it is called transgene flow. However, the biological processes by which transgene flow occurs (*e.g.*, gene flow from a GE corn variety and a non-GE corn variety) and non-transgene flow occurs (*i.e.*, gene flow between two non-GE varieties) are the same.[190]

139. Assuming *arguendo* there were a risk to the life or health of native corn varieties due to the importation of GE corn for dough and tortillas, there are numerous less trade-restrictive measures available to mitigate gene flow between corn plants, irrespective of whether the plant is GE or non-GE. These less trade-restrictive alternatives include adapting co-existence measures that are employed around the world to mitigate cross-pollination between native and non-native crops, such as spatial isolation and natural barriers; clean equipment and storage measures; and community outreach and education.[191] Banning the trade of a commodity for certain uses, especially where no relevant risk assessment has been conducted, is the complete opposite of

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active groups have blocked the planting of transgenic corn and soybeans in Mexico for alleged harm to health, the environment and biodiversity. We reiterate that these disqualifications have no solid scientific basis, are based on partial and biased arguments, and in many cases on lies, such as the harm to health and the environment caused by transgenic crops and glyphosate.") (Exhibit USA-37). Any cross-pollination of genetic material, if it were to occur, would only show up in specific kernels of the cob and would not be present in or otherwise affect the rest of the plant. *See* Brookes et al., at 4-5 (Exhibit USA-170). Those kernels would then need to be planted and cultivated to carry on the transgenic traits. If unintentional transgene flow did theoretically harm the life or health of native corn varieties or wild relatives, those transgenes could be readily bred out and would not persist in the environment. *See, e.g.*, R. Guadagnuolo et al., "Relative Fitness of Transgenic vs. Non-Transgenic Maize x Teosinte Hybrids: A Field Evaluation," 16 ECOLOGICAL SOCIETY OF AMERICA 1967 (Oct. 2006) ("[I]n the absence of selective pressure from glyphosate herbicide, we did not observe any direct positive or negative impact of the transgene on the fitness or vigor of either the hybrids or pure maize progeny. . . . The existence of a physiological cost of the transgene was investigated in the absence of the relevant selective pressure that would have favored the transgenic plants, i.e., no glyphosate was used.") (Exhibit USA-171); L. Liu et al., "Fitness and Ecological Risk of Hybrid Progenies of Wild and Herbicide-Tolerant Soybeans with *EPSPS* Gene," 13 FRONTIERS IN PLANT SCIENCE 1 (June 2022), https://www.frontiersin.org/articles/10.3389/fpls.2022.922215/full (finding that glyphosate-tolerant protein expression was significantly lower in subsequent generations, indicating that transgene presence and any effects would diminish rapidly over time) (Exhibit USA-172).

[190] Mexico claims that "the flow and impact of introduced transgenes is difficult to predict" and "it is not possible to control pollen dispersal." Mexico's Initial Submission, paras. 103, 124. The manner in which pollen flows from a GE corn plant is no different than how it flows from a non-GE corn plant. Countries frequently use isolation distances, barriers, variation in planting times, et cetera to significantly lessen pollen flow between corn varieties.

[191] *See, e.g.*, G. Brookes et al., at 16-17 (Exhibit USA-170); B. M. Baltazar et al., at 1-2 ("Coexistence measures that have been implemented in other geographies, such as spatial isolation, would be successful in Mexico to minimize transgenic maize pollen flow to conventional maize hybrids, landraces and wild relatives.") (Exhibit USA-264); M.A. Sánchez & H. Campos, "Coexistence of Genetically Modified Seed Production and Organic Farming in Chile," 12 GM CROPS & FOOD 509, 513, 516, 518 (2021) (explaining successful coexistence measures include spatial and temporal segregation of fields, transport and storage measures, and post-harvest field management) (Exhibit USA-266); J. Riddle, "A Plan for Co-existence: Best Management Practices for Producers of GMO and Non-GMO Crops," https://misadocuments.info/GMOlegal-21_web.pdf (noting physical buffers, wind direction, and planting dates can all factor into successful co-existence plans, as well as ensuring clean equipment, storage, and transport to avoid inadvertent co-mingling) (Exhibit USA-267).

what the prevailing international standards, guidelines, or recommendations advise to protect plant life and health.[192]

140. In sum, Mexico has provided no logical explanation, let alone scientific support, to show how the Tortilla Corn Ban contributes to its objectives of protecting human and plant life and health. Even if Mexico could muster the relevant support, this measure is applied beyond the extent necessary because there are less trade-restrictive means available that in fact would contribute more to Mexico's stated objectives than the Tortilla Corn Ban. 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 therefore is inconsistent with Article 9.6.6(a) of the USMCA.

### 2. The Substitution Instruction Does Not Address Any Human or Plant Health Risk and Thus Does Not Meet Article 9.6.6(a) of the USMCA.

141. As with the Tortilla Corn Ban, there is no evidence that Mexico's Substitution Instruction is "necessary" to protect human or plant life or health, and it is therefore inconsistent with Article 9.6.6(a) of the USMCA. In fact, Mexico has confirmed that it has set no ALOP for human health with respect to this measure, even though the Substitution Instruction legally mandates that GE corn (but not non-GE corn) be phased out in animal feed and in industrial use for human consumption.[193]

142. If Mexico is concerned about glyphosate residue levels on or in GE corn products, as Mexico has suggested, then it should rely on food and feed MRLs, which are less trade-restrictive measures that are readily available and internationally recognized as a means to protect human (and animal) health. The United States is not aware of any credible evidence that would indicate that Mexico's or the United States' existing MRLs for glyphosate residues in or on corn are inadequate or that GE corn products regularly run afoul of these MRLs. To the contrary, according to USDA's latest data, most commonly there is no detectable glyphosate residue at all on corn grain and, where there are any residues, the levels are *far below* established

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[192] *See also* 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 ("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") (Exhibit-103); Secretariat of the IPPC, *International Plant Protection Convention*, arts. VII.1-2 (1997), https://www.ippc.int/en/publications/131/ ("In 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.") (Exhibit USA-102).

[193] *See, e.g.*, Mexico's Initial Submission, para. 344.

tolerance levels.[194] If Mexico had a legitimate, scientifically supportable concern about the risk of glyphosate residue on corn, it should have relied on that science to inform its MRLs, which apply to both GE and non-GE corn.[195]

143. Likewise, even if Mexico could show that GE corn imports intended for animal feed or for industrial use for human consumption have affected the genetic composition of Mexico's native corn varieties,[196] the United States is not aware of any scientific evidence supporting that such changes would affect the health of the plant, *i.e.*, present a risk to plant life or health—and the Mexican government has confirmed this understanding in judicial proceedings.[197] Assuming *arguendo* that Mexico could establish that the importation of GE corn presents a risk to the life or health of Mexico's native corn varieties, there are less trade-restrictive measures that would be readily available to achieve the same level of protection, such that the Substitution Instruction is not "necessary." These less trade-restrictive alternatives include enforcing or strengthening remediation procedures under the Biosafety Law to regulate and sanction unauthorized behavior such as illegal GE corn cultivation; adapting co-existence measures that are employed around the world to mitigate cross-pollination between native and non-native crops, such as spatial isolation and natural barriers; clean equipment and storage measures; and community outreach and education.[198]

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[194] *See, e.g.*, USDA AMS, PESTICIDE DATA PROGRAM, ANNUAL SUMMARY, CALENDAR YEAR 2022, at Appendix C (Jan. 2024), https://www.ams.usda.gov/sites/default/files/media/2022PDPAnnualSummary.pdf (finding that three-fourths of sampled corn grain had no detectable glyphosate residue at all, and that the remaining one-fourth had levels significantly below tolerance levels) (Exhibit USA-254).

[195] In addition, if Mexico is concerned about animal-derived commodities that may have been exposed to *glyphosate residue* through corn feed, Codex and other international regulators have established MRLs for glyphosate residues in animal-derived commodities. *See, e.g.*, Codex Alimentarius, "Glyphosate – Pesticides Database Search" (including MRLs for animal-derived commodities) (Exhibit USA-235); European Commission, "Glyphosate – Pesticide Residue(s) and Maximum Residue Levels (mg/kg)" (including MRLs for animal-derived commodities) (Exhibit USA-236); EPA, 40 C.F.R. 180.364, "Glyphosate; tolerances for residues" (including MRLs for animal-derived commodities) (Exhibit USA-237).

[196] *See supra* Section IV.B.1 (explaining why, as a scientific matter, transgene flow from imported GE corn intended for food or feed use is unlikely).

[197] Judicial Branch of the Federation of the United Mexican States, Final Judgment 321/2013-I, at 4-5, 15-16 (Sept. 28, 2023) (English excerpt) (Exhibit USA-165).

[198] *See, e.g.*, G. Brookes et al., at 16-17 (Exhibit USA-170); B. M. Baltazar et al., at 1-2 ("Coexistence measures that have been implemented in other geographies, such as spatial isolation, would be successful in Mexico to minimize transgenic maize pollen flow to conventional maize hybrids, landraces and wild relatives.") (Exhibit USA-264); M.A. Sánchez & H. Campos, "Coexistence of Genetically Modified Seed Production and Organic Farming in Chile," 12 GM CROPS & FOOD 509, 513, 516, 518 (2021) (explaining successful coexistence measures include spatial and temporal segregation of fields, transport and storage measures, and post-harvest field management) (Exhibit USA-266); J. Riddle, "A Plan for Co-existence: Best Management Practices for Producers of GMO and Non-GMO Crops," https://misadocuments.info/GMOlegal-21_web.pdf (noting physical buffers, wind direction, and

144. 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 Instruction is therefore inconsistent with Article 9.6.6(a) of the USMCA.

### C. Mexico's Measures are Not Based on Relevant Scientific Principles, Contravening Article 9.6.6(b) of the USMCA.

145. To recall, Article 9.6.6(b) provides that "[e]ach party shall ensure that its sanitary and phytosanitary measure . . . are based on relevant scientific principles, taking into account relevant factors, including, if appropriate, different geographic conditions." Neither the Tortilla Corn Ban nor the Substitution Instruction is based on relevant scientific principles, as required under Article 9.6.6(b) of the USMCA.

146. As an initial matter, Mexico does not present any arguments in its Initial Submission to contest that the Substitution Instruction is inconsistent with Article 9.6.6(b).[199] Thus, this U.S. claim remains unrefuted with respect to the Substitution Instruction.

147. As the United States explained in its Initial Submission, WTO panels, in assessing this provision, have 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.[200] The United States has already established that Mexico did not conduct anything approaching an appropriate risk assessment prior to instituting the Tortilla Corn Ban. Mexico's primary argument with respect to Article 9.6.6(b) is the hollow assertion that the measure is "based on a thorough and robust review of scientific studies, data, and analyses,"[201] but Mexico's "risk assessment" is nothing more than an amalgamation of selected sources, pursuant to no particular methodology, and summarized at a high level in a document that largely has nothing to do with risks to human health from consumption of GE corn in dough or tortillas. Even if the content were relevant, Mexico did not conduct a case-by-case assessment of GE events as required under international standards and reinforced by Mexico's own judicial system.[202] Mexico's "risk assessment" also did not address how GE corn imported for use in dough and tortillas presents an actual risk to its native corn varieties, nor could Mexico do so because its government agencies have already

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planting dates can all factor into successful co-existence plans, as well as ensuring clean equipment, storage, and transport to avoid inadvertent co-mingling) (Exhibit USA-267).

[199] Section VII.E.6 of Mexico's Initial Submission addresses the Corn Tortilla Ban under Article 9.6.6(b), but there is no equivalent section addressing the Substitution Instruction under this provision.

[200] *See* Panel Report, *Australia – Apples*, paras. 7.472, 7.510, 7.779, 7887, 7.905, 7.1308 (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) (Exhibit USA-122).

[201] Mexico's Initial Submission, para. 430.

[202] *See supra* Section IV.A.

testified in a court of law that they have no data to support this position.[203]

148. Mexico's additional arguments, contending conformity to Article 9.6.6(b), are generic and do nothing to reinforce that Mexico followed scientific principles. Mexico alleges it took into account "'relevant factors to Mexico,' namely the central role of corn" and the "current patterns of corn consumption" without citing any scientific support, let alone a relevant risk assessment that captures an evaluation of hazard, exposure, and risk with respect to Mexican consumption patterns.[204] Mexico also argues that the Tortilla Corn Ban "is tailored to the specific risk of glyphosate residues in foods made with GM corn and limits the effect of any restriction to the specific use of GM corn," offering a trade-restrictiveness argument that, without citation, evinces no reasoning from scientific principles.[205]

149. Mexico's final argument, without citing any support, is that "the scientific evidence on the risk of displacement of native corn varieties is well documented," and "restricting the use of GM corn for flour processing" is necessary to "address[] the risk of diversion of GM corn kernels."[206] As the United States has explained, the Tortilla Corn Ban—banning the use of GE corn in dough and tortillas—has no scientific or logical connection to protecting the plant life or health of native corn varieties.[207] Mexican government agencies have conceded that they have no documentation of any unauthorized release (let alone release of GE corn imported for use in dough and tortillas) nor any evidence of actual harm to native varieties.[208]

150. Mexico's Biotechnology Committee of the Mexican Academy of Sciences has stated that there is "no solid scientific basis" to the allegations of harm to health and the environment caused by GE crops or glyphosate residues.[209] In sum, the Tortilla Corn Ban is not based on

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[203] Judicial Branch of the Federation of the United Mexican States, Final Judgment 321/2013-I, at 4-5, 15-16 (Sept. 28, 2023) (English excerpt) (Exhibit USA-165).

[204] Mexico's Initial Submission, para. 431.

[205] *Id.*, para. 432. Mexico has not provided a risk assessment that shows GE corn, at the point of consumption, has higher glyphosate residue levels than non-GE corn, nor has Mexico shown that any such residue levels would present a risk to human health based on Mexican consumption patterns. *See also* Annex II (addressing Mexico's statements regarding agrochemical usage and GE crops).

[206] *Id.*, para. 433.

[207] *See supra* Section IV.B.

[208] Judicial Branch of the Federation of the United Mexican States, Final Judgment 321/2013-I, at 4-5, 15-16 (Sept. 28, 2023) (English excerpt) (Exhibit USA-165).

[209] Biotechnology Committee of the Mexican Academy of Sciences, at 350-351 ("By means of amparos [constitutional protections] and lawsuits – some of them filed before the judiciary – certain opposition and very active groups have blocked the planting of transgenic corn and soybeans in Mexico for alleged harm to health, the environment and biodiversity. We reiterate that these disqualifications have no solid scientific basis, are based on partial and biased arguments, and in many cases on lies, such as the harm to health and the environment caused by transgenic crops and glyphosate.") (Exhibit USA-37).

relevant scientific principles.

151. Mexico also offers no argument at all to refute that the Substitution Instruction contravenes Article 9.6.6(b).[210] Thus, both the Tortilla Corn Ban and the Substitution Instruction are not based on scientific principles and thus do not comply with Mexico's USMCA obligation.

### D. Mexico Has No Documented Risk Assessment or Risk Management and Did Not Afford Other Parties an Opportunity to Comment under Article 9.6.7 of the USMCA.

152. The United States maintains that Mexico did not complete a risk assessment consistent with its SPS obligations. Even if the Panel were to determine that the CONAHCYT Dossier and an alleged database of SNIB articles constitute a risk assessment, the Tortilla Corn Ban and Substitution Instruction 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. In addition, Mexico does not dispute that it did not document its risk management process for the Tortilla Corn Ban or the Substitution Instruction, nor did the United States have an opportunity to comment on it, such that Mexico has offered no rebuttal to the U.S. claims under Article 9.6.7 of the USMCA.[211]

153. Over the many years in which the United States and Mexico discussed measures related to agricultural biotechnology, and specifically raised concerns about the evolving import restrictions on U.S. GE corn, not once did Mexico identify the CONAHCYT Dossier or a SNIB database as its risk assessment, despite repeated requests from the United States for copies of any risk assessment. Accordingly, the United States never had an opportunity to comment on these alleged "risk assessment" documents.

154. Similarly, Mexico remains unable to identify any documented risk management process. Risk management is a separate and distinct process that concerns "the weighing of policy alternatives in light of the results of [a] risk assessment," and may or may not include SPS measures.[212] Mexico has not demonstrated any documented weighing of policy alternatives. Indeed, when 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, Mexico simply announced the 2023

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[210] Section VII.E.6 of Mexico's Initial Submission addresses the Corn Tortilla Ban under Article 9.6.6(b), but there is no equivalent section addressing the Substitution Instruction under this provision.

[211] *See* Mexico's Initial Submission, Section VII.E.3 (only addressing Mexico's alleged risk assessment process and making no mention of a documented risk management process).

[212] USMCA, art. 9.1.2; *see also* Codex Principles, sec. 3, para. 16 (Exhibit USA-113); Secretariat of the IPPC, *Framework for Pest Risk Analysis*, sec. 2.3 (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).

Corn Decree and never substantively responded.[213] Mexico's Initial Submission does not even purport that Mexico has documented its risk management process or provided the United States with an opportunity for comment on it.[214]

155. The United States was not provided an opportunity to comment on any risk assessment or risk management prior to the issuance of the Tortilla Corn Ban or the Substitution Instruction, nor did Mexico document any risk assessment or risk management. As a result, these measures are inconsistent with Article 9.6.7 of the USMCA.

### E. Neither Measure Took Into Account Relevant International Standards or Available Relevant Scientific Evidence, Contrary to Article 9.6.8 of the USMCA.

156. Even if Mexico had conducted the requisite risk assessment and risk management to evaluate the potential for 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), such risk assessments and risk management must have "take[n] into account . . . the relevant international standards, guidelines, and recommendations of the relevant international organization" and "the available relevant scientific evidence," which Mexico did not do.[215]

157. According to the relevant international standards, a risk assessment should be based on "scientific data,"[216] use "sound scientific methods,"[217] be performed on a "case-by-case basis,"[218] and the resulting SPS measure should be "technically justified."[219] Mexico's purported risk assessment did not follow any of these principles. In endeavoring to show that it conformed to Article 9.6.8, Mexico asserts in Section VII.E.4.b of its Initial Submission that its risk assessment took into account a variety of studies, the vast majority of which were not even cited in the CONAHCYT Dossier.[220] Mexico's post hoc justification of its measures is out of step with

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[213] *See* U.S. Initial Submission, paras. 60-61.

[214] Mexico's Initial Submission, paras. 395-399.

[215] USMCA, art. 9.6.8.

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

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

[218] Codex Principles, sec. 3, paras. 10, 12 (Exhibit USA-113).

[219] *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).

[220] *See, e,g.*, Mexico's Initial Submission, n.428 (citing MEX-306), n.429 (citing MEX-307), n.430 (citing MEX-308), n.431 (citing MEX-309), n.432 (MEX-310), n.435 (citing MEX-193); n.439 (citing MEX-139), n.440 (citing MEX-313), n.441 (citing MEX-314), n.442 (citing MEX-315), n.443 (citing MEX-316 and MEX-317), n.445 (citing

relevant international standards and the SPS Chapter itself, both of which provide that an SPS measure must be based on the risk assessment.[221] And even if one assumes that Mexico's risk assessment did take into account these studies, the studies are either irrelevant or do not purport to show what Mexico claims.[222] In contrast, Mexico did not take into account the very relevant scientific evidence—the multitude of risk assessments performed or evaluated by regulators around the world, confirming the safety of commercialized GE corn events. Any risk assessment therefore did not take into account the relevant scientific evidence demonstrating the safety of GE corn, including those events previously authorized by Mexico.

158. In addressing the Article 9.6.8 claim, Mexico acknowledges that Codex MRLs are relevant international standards that address maximum residues of glyphosate on certain commodities, including corn;[223] nevertheless, Mexico dismisses the Codex MRLs as "insufficient to address Mexico's level of protection," because Mexicans consume a lot of corn.[224] In order to establish a tolerance (*i.e.*, an MRL), a regulatory agency must first make a safety finding using a risk assessment, which typically takes into account nationally representative consumption data. A country may adopt the Codex MRLs for the particular pesticide and commodity, or countries may choose to deviate from these levels based on a risk assessment. Indeed, although Mexico does not acknowledge it, Mexico has traditionally recognized a 1.0 ppm MRL for glyphosate residues, which departs from the Codex MRL, so Mexico is well aware that the Codex MRLs need not be adopted directly. In adopting the Tortilla Corn Ban and the Substitution Instruction, Mexico has not demonstrated through a risk assessment why its prior MRL was insufficient.

159. Mexico also cannot now claim that its regulators—*i.e.*, COFEPRIS—did not or could not account for Mexicans' "unique" dietary patterns when evaluating the safety of GE corn events at the time of authorization. Since the introduction of Mexico's Biosafety Law in 2005, authorization of a GE corn event by COFEPRIS, including recent COFEPRIS authorizations, must be predicated on a dietary risk assessment that takes into account the "use and consumption

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MEX-319), n.446 (citing MEX-320), n.447 (citing MEX-321), n.448 (citing MEX-322), n.449 (citing MEX-323), n.450 (citing MEX-005), n.453 (citing MEX-324).

[221] *See supra* Section IV.A.

[222] *See* Annex III (reviewing articles cited in Section VII.E.4.b of Mexico's Initial Submission).

[223] To be clear, MRLs are used for enforcement purposes and, while based on risk assessments and safety findings, are not one and the same as those things, as Mexico suggests. *See, e.g.*, Mexico's Initial Submission, para. 422.

[224] *Id.*, paras. 420-423. Mexico makes the unsupported allegation that because Mexico allegedly consumes 10 times more corn products than the average U.S. consumer, "the average person's exposure to dietary glyphosate from GM corn is 10 times higher in Mexico than in the United States." It is difficult to square this baseless assumption with Mexico's argument that most of its corn used in dough and tortillas is domestically sourced. *See id.*, para. 237. Even taking into account Mexico's corn consumption patterns, the United States is not aware of any risk of concern from dietary exposure.

conditions in Mexico," consistent with the Codex Guidelines.[225]

160. Accordingly, when applicants submit authorization requests to COFEPRIS, these applicants must provide a Mexico-specific dietary exposure risk assessment for the particular GE event. Mexican human consumption data for food and feed safety assessments come directly from *The Diet of Mexicans*, published by the Mexican National Chamber of the Manufacturing Industry.[226] [redacted][227]

161. Mexico's repeated argument that its level of corn consumption eliminates its obligation under the USMCA to abide by international standards and scientific principles, or leaves open the question of whether approved GE corn events are safe, is baseless.[228] COFEPRIS already took into account the "special consideration" of Mexico's high corn consumption in its risk assessments authorizing GE corn varieties for food and feed.[229] Moreover, COFEPRIS has expressly acknowledged that that the Codex Guidelines are the relevant guidelines for conducting safety assessments of GE food.[230] There is nothing unique about the level of consumption of corn in Mexico that would make it inappropriate to apply standard risk

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[225] *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).

[226] Mexican National Chamber of the Manufacturing Industry, *The Diet of Mexicans*, at 92-93, https://apiperiodico.jalisco.gob.mx/api/sites/periodicooficial.jalisco.gob.mx/files/la_alimentacion_de_los_mexicanos_-_pedro_garcia_uriguen.pdf (Exhibit USA-215). These values are utilized to determine the intake of a certain protein to obtain the highest estimated chronic intake of a protein from consumption of the grain, and then compared to the acute toxicity study completed for that protein. These safety assessments conservatively assume that the new GE corn event makes up 100 percent of the corn product consumed by an individual and that no degradation of the newly expressed protein occurs. Typically corn is subjected to certain processing steps, such as cooking, before being consumed by humans; these steps often degrade or denature the protein, thereby decreasing potential exposure.

[227] *See* [redacted] (Exhibit USA-216).

[228] *See, e.g.*, Mexico's Initial Submission, paras. 61, 120, 174, 341, 382, 423-424.

[229] Notably, Mexico has not even alleged that Mexican dietary patterns have changed since these GE events were first authorized for importation and sale.

[230] FAO GM Foods Platform, Mexico – Country Profile (affirming that Mexico "follows the relevant Codex Guidelines or national/regional guidelines that are in line with the Codex Guidelines in conducting safety assessment of GM food") (last modified Oct. 19, 2023) (Exhibit USA-217).

assessment principles and guidelines to assess the risk of consuming GE corn varieties.[231]

162. Similarly, Mexico acknowledges that the SPS Agreement identifies the IPPC standards as relevant to plant health, but Mexico again repudiates these standards on the basis that these standards do not take into account the "predominant agricultural practices in Mexico . . . and the natural biodiversity of unique native varieties and landraces of corn."[232] Mexico has not identified what about Mexico's agricultural practices and natural biodiversity uniquely render the standards inapplicable to Mexico. The whole point of the framework is that it is to be tailored to a particular set of circumstances; if each country could invoke its unique agricultural practices as a reason for the standards not to apply, then there would be little point to having international standards. 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, determined whether the organisms are indeed pests, and assessed their introduction and spread, along with the economic impacts—none of which Mexico completed.[233] The likeliest reason why this process was not performed is because there was no pest to assess and no health risk to native varieties to document, as Mexican government agencies have

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[231] The Codex Guidelines—the relevant international standards that Mexico has now, without explanation, alleged to be irrelevant—expressly address that "[c]onsumption patterns will vary from country to country depending on the importance of the food in the diet(s) of a given population(s)," and therefore recommends "that consumption estimates [be] based on national or regional food consumption data when available." Codex Guidelines, sec. 3, para. 16 (Exhibit USA-114). It is commonly understood that populations may consume higher or lower amounts of particular foods; differences in consumption do not preclude the ability to estimate dietary exposure and risk. As just one example, South Africa consumes large volumes of corn and has been able to conduct a risk assessment for glyphosate-tolerant GE corn (as well as *Bt* cultivars), in accordance with the Codex Guidelines, and has been an ardent adopter of GE corn. *See, e.g.*, USDA FAS & GAIN, "South Africa – Agricultural Biotechnology Annual," at 1-2, 5-11, 36-43 (Dec. 4, 2023) (Exhibit USA-218); FAO GM Foods Platform, South Africa – Country Profile (last modified Apr. 2018) (recognizing Codex Guidelines) (Exhibit USA-219); *see also* K. Ala-Kokko et al., "Economic and Ecosystem Impacts of GM Maize in South Africa," 29 GLOBAL FOOD SECURITY 1, 8 (2021) ("Using a combined economic (province-level yield benefits of GM and adoption rates) and environmental (LCA) approach, we estimate the total welfare benefits attributable to GM white maize adoption in South Africa for 2001–2018 are $694.7 million. Food security benefits attributable to GM white maize also manifest through an average of 4.6 million additional rations annually.") (Exhibit USA-220); A. Shew et al., "Yield Gains Larger in GM Maize for Human Consumption than Livestock Feed in South Africa," 2 NATURE FOOD 104 (2021) ("In South Africa, GM white maize has been grown for direct human consumption alongside GM yellow maize and conventional hybrid (CH) maize for livestock feed since 1999. No major GM staple food crop is believed to have been tested and commercially produced as much as GM white maize in South Africa.") (Exhibit USA-221).

[232] Mexico's Initial Submission, para. 427.

[233] 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).

confirmed in legal proceedings.[234]

163. To summarize, there is no scientific evidence of a risk to humans, animals, or plants from commercialized GE corn varieties used in dough and tortillas, in animal feed, or in industrial food uses. Mexico's purported "risk assessment" did not take into account the abundant evidence of safety. Mexico's own Biotechnology Committee of the Mexican Academy of Sciences has not been able to identify a single credible case of harm to human health or the environment from GE plants,[235] further reinforcing that Mexico has not taken into account all of the available relevant scientific evidence. Because any risk assessment that Mexico may have performed did not take into account all the available scientific evidence and, by Mexico's own admission, did not account for the applicable international standards, Mexico's measures are inconsistent with Article 9.6.8 of the USMCA.

### F. Mexico Has Not Refuted That Both Measures Are More Trade-Restrictive Than Required Under Article 9.6.10 of the USMCA.

164. The Tortilla Corn Ban and the Substitution Instruction are inconsistent with Article 9.6.10 of the USMCA, because these measures are more trade-restrictive than required to achieve the vague ALOP that Mexico now suggests is appropriate.[236]

165. Mexico appears to allege that because it has asserted "zero risk" as its human health ALOP for the Tortilla Corn Ban, the relevant MRLs that Mexico previously applied to corn are now inadequate (with respect to GE corn only), and the only solution is for Mexico to ban the use of GE corn altogether. Mexico's position reflects a fundamental misunderstanding of risk, and reflects a dramatic shift in policy with no corresponding shift in the underlying science.

166. Dietary risk is a function of exposure and toxicity. A regulator needs both parts (how much exposure, how much toxicity) to determine the risk, and risk estimates should be characterized. Rather than performing a risk assessment that assesses these two key components, however, Mexico purports to have "relied on existing scientific literature and studies."[237] Yet none of these studies addresses both exposure to and toxicity of glyphosate residue on or in GE corn (or any of the other health risks alleged)—let alone in terms of Mexico's consumption pattern—and therefore cannot be relied on to identify a human health concern at any level of exposure.

167. Rather than performing an assessment to identify if and at what point a risk to human

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[234] Judicial Branch of the Federation of the United Mexican States, Final Judgment 321/2013-I, at 15-16 (Sept. 28, 2023) (English excerpt) (Exhibit USA-165).

[235] Biotechnology Committee of the Mexican Academy of Sciences, at 27-28 (Exhibit USA-37).

[236] *See supra* Section IV.A (explaining the deficiencies in Mexico's alleged ALOPs).

[237] Mexico's Initial Submission, para. 422.

health might arise, Mexico has simply asserted a "zero risk" ALOP as its carte blanche justification for taking the most draconian measure available to it—a ban on the use of GE corn in dough and tortillas and ultimately in all other food for human or animal consumption. That approach is both unscientific and clearly more trade-restrictive than necessary.

168. The second sentence of Article 9.6.10 of the USMCA clarifies that a measure is inconsistent 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.

169. Fundamentally, it is not clear how Mexico's Tortilla Corn Ban even achieves a "zero risk" ALOP, as this measure does not ban non-GE corn, which may also be treated with glyphosate. The Tortilla Corn Ban also does not ban the importation or sale of other crops—whether GE or non-GE—such as soybean, canola, or cotton, which may be grown domestically in Mexico or internationally with the aid of glyphosate. The fact that Mexico has "tailored" the Tortilla Corn Ban to focus just on GE corn is not an indication that Mexico has shown restraint in terms of trade-restrictiveness but rather just underscores that Mexico has targeted GE corn without scientific justification, and Mexico has not presented any credible risk assessment to justify this position. Even if Mexico were able to identify a health concern related to some level of dietary intake of glyphosate residues on GE corn, a significantly less trade-restrictive measure that is reasonably available would be for Mexico to continue implementing its MRLs for glyphosate.[238]

170. Similarly, to the extent the Tortilla Corn Ban is intended to protect plant life or health, on the basis that imported GE corn will cross-pollinate with native varieties, the Tortilla Corn Ban does not achieve Mexico's ALOP for native corn protection because Mexico has not submitted any scientific evidence that transgene flow impacts the plant life or health of native corn varieties.[239] Even putting aside the flawed proposition that authorized imports of GE corn (which cannot legally be planted in Mexico) threaten native varieties' life or health because of possible transgene flow, the United States notes that the Tortilla Ban fails to address this threat, because it does not prohibit the importation of all GE corn, or the importation, domestic cultivation, or sale of non-GE corn that is not a native variety. Finally, Mexico can point to no scientific determination in its purported risk assessment that stopping authorized imports of GE corn for food and feed would actually eliminate or substantially limit transgene flow into native

[238] *See supra* Section IV.B (further explaining how MRLs, rather than the Tortilla Corn Ban, more effectively address any alleged ALOP).

[239] *See, e.g.*, Biotechnology Committee of the Mexican Academy of Sciences, 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); Judicial Branch of the Federation of the United Mexican States, Final Judgment 321/2013-I, at 4-5, 16 (Sept. 28, 2023) (excerpt) (Exhibit USA-165).

corn varieties. Mexico has simply not assessed this risk.[240]

171. Even if Mexico were able to identify a risk to plant health related to the importation of GE corn for use in dough and tortillas, there are many significantly less trade-restrictive measures that are reasonably available to Mexico that would contribute to Mexico's goal of "mitigat[ing] the damage caused to native corn by slowing or stopping the rate of transgression"[241] at least as effectively, if not more effectively, than the Tortilla Corn Ban. These measures include adapting co-existence measures that are employed around the world, such as spatial isolation, natural barriers, and clean equipment and storage measures, to mitigate cross-pollination between native and non-native corn crops; enforcing or strengthening remediation procedures under the Biosafety Law to regulate and sanction unauthorized behavior such as illegal GE corn cultivation; continuing or strengthening existing in situ (environment) and ex situ (germplasm banks) conservation measures and adopting new ones; community outreach and education efforts; et cetera.[242]

172. At bottom, because the Tortilla Corn Ban does not achieve any ALOP against a human or plant health risk, a reasonably available, less trade-restrictive alternative would be to withdraw it altogether. However, even if the Tortilla Corn Ban contributed to Mexico's ALOP, there are less trade-restrictive alternatives that are readily available for Mexico to utilize.

173. For the same reasons as set out above with respect to the Tortilla Corn Ban, Mexico's Substitution Instruction is inconsistent with Article 9.6.10 of the USMCA, because this measure is more trade-restrictive than required to achieve any purported ALOP with respect to human health or native corn varieties.[243]

174. Accordingly, the Tortilla Corn Ban and the Substitution Instruction, respectively, are inconsistent with Article 9.6.10 of the USMCA.

## V. MEXICO ERRS IN ARGUING THAT USMCA ARTICLE 2.11 IS NOT APPROPRIATE TO DETERMINE THE MEASURES' CONSISTENCY WITH MEXICO'S USMCA COMMITMENTS.

175. In its Initial Submission, Mexico questions whether the United States properly challenged the Tortilla Corn Ban and the Substitution Instruction under Article 2.11 of the USMCA. In this section, the United States will argue (i) that it properly challenged Mexico's measures under

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[240] Mexico has not characterized the hazard or assessed the various possible routes and levels of transgene flow, as required in a risk analysis. *See supra* Section IV.A.

[241] Mexico Initial Submission, para. 346.

[242] *See supra* Section IV.B.

[243] As noted previously, Mexico has not defined a human health ALOP for the Substitution Instruction.

USMCA Article 2.11 and (ii) that Mexico's measures constitute a prohibition or restriction on the importation of GE corn inconsistent with Article 2.11 of the USMCA.

### A. The United States Properly Challenges Mexico's Measures under Article 2.11 of the USMCA.

176. Mexico argues that the Tortilla Corn Ban and the Substitution Instruction are "domestic measures . . . governed by Article III of GATT 1994 (and the equivalent provisions of the USMCA), and not by Article XI.1 (and Article 2.11.1 of the USMCA)."[244] In its Initial Submission, Mexico relies heavily on narrow and uncontextualized statements pulled from the *India – Autos* WTO panel report to support its assertion that the Tortilla Corn Ban and the Substitution Instruction are domestic in nature and the U.S. claims are better governed by Article III (USMCA Article 2.3).[245] However, as the United States will demonstrate below, *India – Autos* actually supports the U.S. challenge to Mexico's measures under Article 2.11.

177. The WTO panel asserted that "[t]he use of the term 'importation' in Article XI, rather than 'imports', or 'imported products', clearly suggests that what is targeted in Article XI:1 is exclusively those restrictions which relate to the importation itself, and not to *already* imported products."[246]

178. It is evident that Mexico's measures are related to the importation, or process of importing, of GE corn. The Tortilla Corn Ban explicitly states that Mexico's biosafety authorities "shall revoke and refrain from issuing authorizations for the use of genetically modified corn grain for human consumption."[247] The biosafety authorities' decision to issue, revoke, or refrain from granting authorizations for the commercialization and importation of GE products is *directly* related to the process of importing GE corn into Mexico; without an authorization GE corn cannot enter Mexico. In addition, the Substitution Instruction has the explicit directive to "conduct the gradual substitution of genetically modified corn for animal feed and industrial use for human consumption," essentially restricting all imported GE corn into Mexico.[248]

179. Mexico states, without explanation, that a "purposive" and "contextual" interpretation of its measures demonstrates that the Tortilla Corn Ban and the Substitution Instruction are domestic measures designed to regulate the end use of GE corn, and any relation to the

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[244] Mexico's Initial Submission, para. 457.

[245] Mexico's Initial Submission, paras. 458-459.

[246] Panel Report, *India – Measures Affecting the Automotive Sector*, WT/DS146/R, WT/DS175/R, para. 7.259 (adopted Apr. 5, 2002) (Exhibit USA-129).

[247] 2023 Corn Decree, art. 6(II) (Exhibit USA-3).

[248] 2023 Corn Decree, art. 7 (Exhibit USA-3).

importation of GE corn is secondary.[249] However, there is no reasoning provided by Mexico to substantiate this assertation, and just because Mexico contends its measures are focused on domestic regulation rather than international trade does not mean the Panel should accept it. [250]

180. To that end, we note that the 2023 Corn Decree cites self-sufficiency in directing its government authorities to "abstain from […] promoting and importing genetically modified corn,"[251] and requiring the eventual complete replacement of imported GE corn for any purpose. In addition, Mexico's Initial Submission also provides evidence that its measures are designed to address the importation of GE corn. Specifically, Mexico notes that the Tortilla Corn Ban and the Substitution Instruction are necessary to prevent the "dominance of GM corn in the marketplace" and the displacement of corn grown by Mexican farmers.[252]

181. Accordingly, it is clear that the challenged measures fall comfortably within the disciplines of USMCA Article 2.11.

### B. Mexico's Tortilla Corn Ban and Substitution Instruction Constitute a Prohibition or Restriction on the Importation of a Good of Another Party that is Inconsistent with Article 2.11.

182. Mexico also argues that, even if its measures fell within the scope of Article 2.11, they would be consistent with that provision.

183. Article 2.11 of the USMCA 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 (iii) the measure is not "otherwise provided" for in the USMCA. Mexico only discusses the consistency of its measures with the first of the aforementioned elements—that is, whether its measures can be characterized as a "prohibition or restriction"—and does not contest that the latter two elements are met.

184. According to Mexico, the Tortilla Corn Ban and the Substitution Instruction do not constitute prohibitions or restrictions on the importation of any good.[253] However, Mexico's argument is not really about whether the design and operation of the challenged measures

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[249] Mexico's Initial Submission, para. 459.

[250] For example, one WTO report considered that that "the underlying purpose and centre of gravity of the measures rather than how the respondent classified or fashioned the challenged measure" is imperative for determining the correct GATT discipline for review. Panel Report, *Indonesia - Measures Relating to Raw Materials*, WT/DS592/R, para. 7.60 (circulated to WTO Members Nov. 30, 2022) (referencing the panel and Appellate Body reports in *China – Measures Affecting Imports of Automobile Parts*) (adopted Apr. 5, 2002)) (Exhibit USA-282).

[251] 2023 Corn Decree, art. 3(I) (Exhibit USA-3).

[252] Mexico's Initial Submission, para. 497.

[253] Mexico's Initial Submission, para. 474.

constitute a restriction or limitation within the ordinary meanings of those words. Rather, Mexico focuses on its contention that the measures are domestic in nature, and applied horizontally, rather than applied specifically to importation.

185. In many ways, this argument suffers from the same flaw as its earlier argument that the U.S. claim should be governed by Article III of the GATT 1994 instead of Article XI:1—namely, that domestic application in no way forecloses a measure from restricting or limiting importation. Mexico effectively relies on its contention that "the prohibition or restriction cannot be so broad as to cover any domestic measure regulating how products are marketed and sold within a country's territory."[254]

186. Prior WTO panels have noted "that the text of Article XI:1 is very broad in scope, providing for a general ban on import or export restrictions or prohibitions 'other than duties, taxes or other charges.' The scope of the term 'restriction' is also broad, as seen in its ordinary meaning, which is 'a limitation on action, a limiting condition or regulation.'"[255] Furthermore, 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.[256]

187. Similarly here, the Tortilla Corn Ban is specifically aimed at limiting the importation of certain GE corn in pursuit of self-sufficiency policies designed to encourage domestic production. Both the gradual phase-out and the completed substitution place a "limiting condition" on importation, and therefore constitute a "restriction" under the ordinary meaning of "prohibition or restriction" on importation for purposes of Article 2.11.[257]

188. Mexico also attempts to argue that the Tortilla Corn Ban and Substitution Instruction have not blocked or restricted trade, specifically the importation of such goods. Mexico is wrong on what is required to establish a breach of Article XI and the facts in this case.

189. As the reports in *Argentina – Import Measures* noted, a limitation under Article XI "need not be demonstrated by quantifying the effects of a measure at issue; rather, such limiting effects

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[254] Mexico's Initial Submission, para. 472.

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

[256] 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).

[257] *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).

can be demonstrated through the design, architecture, and revealing structure of the measure at issue considered in its relevant context."[258] As discussed above, the measures clearly restrict trade. Moreover, WTO panel reports have repeatedly noted that this provision protects competitive opportunities, not trade flows.[259]

190. In any event, the measures have already had trade effects. U.S. exports of white corn significantly declined year-on-year in 2023. In the eleven months that elapsed since the enactment of the 2023 Corn Decree (the latest data available), U.S. white corn exports to Mexico, by volume, declined by approximately 40 percent year-on-year and by 50 percent in total value as a result of Mexico's measures restricting the use of GE corn.[260] In addition, [redacted]

191. Furthermore, Mexico argues that the Substitution Instruction has not been applied, which the United States has already rebutted in Section III.[261] But, in making this argument, Mexico asserts that "it contemplates internal actions that will apply similarly to all GM corn grain, regardless of origin."[262] Thus, Mexico apparently does not find it impossible to discern the measure's operation from its structure when in service of arguments Mexico finds useful. (Of course, as a factual matter, Mexico's assertion cannot be squared with the myriad evidence that the whole point is to substitute domestic corn for imported GE corn.)

192. As outlined in the U.S. Initial Submission, and reiterated above, these measures are clearly restrictions affecting the importation of GE corn. Accordingly, Mexico's attempt to rebut the United States' Article 2.11 claim fails.

## VI. MEXICO'S CLAIM OF CONSISTENCY WITH USMCA ARTICLE 24.15.2 IS IRRELEVANT TO THIS DISPUTE.

193. Mexico contends that its Tortilla Corn Ban and Substitution Instruction are consistent with the provisions of Article 24.15 (Trade and Biodiversity) of the USMCA, specifically Article 24.15.2, which states that "each Party shall promote and encourage the conservation and

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[258] 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) (referring to Appellate Body Reports, *China – Raw Materials*, paras. 319-320) (Exhibit USA-131).

[259] *See, e.g.*, Panel Report, *Argentina – Measures Affecting the Importation of Goods*, WT/DS438/R, WT/DS444/R, WT/DS445/R, paras. 6.453-6.455 (adopted Jan. 26, 2015) (Exhibit USA-281).

[260] U.S. Census Bureau Data, "U.S. Corn Exports to Mexico 2022-Jan. 2024" (Exhibit USA-229).

[261] *Supra* Section II.C.

[262] Mexico's Initial Submission, para. 474.

sustainable use of biological diversity, in accordance with its law or policy."[263] But Mexico stops short of drawing any legal relevance from this contention. There is none.

194. Article 24.15.2 does not operate as an exception that provides an affirmative defense to breaches of other provisions of the USMCA. And the United States has not brought claims under Article 24.15.2. Accordingly, this provision is irrelevant to this dispute.

195. The Panel has already reached the same conclusion. The Asociación Nacional de Empresas Comercializadoras de Productores del Campo A.C. ("ANEC") submitted an application for leave and asserted the measures are consistent with "Chapter 3 (agriculture) and 24 (environment)" of the USMCA.[264] In response, the Panel determined that ANEC's written views should "[exclude] any discussion of Chapters 3 and 24 of the USMCA, which are not before this Panel."[265]

## VII. MEXICO DOES NOT SATISFY THE REQUIREMENTS OF ARTICLE XX(A) OR ARTICLE XX(G) WITH RESPECT TO THE TORTILLA CORN BAN AND THE SUBSTITUTION INSTRUCTION.

196. The United States demonstrated in its Initial Submission that Mexico's Tortilla Corn Ban and Substitution Instruction are inconsistent with several of Mexico's USMCA commitments under the SPS Chapter and National Treatment and Market Access for Goods Chapter. Mexico contends that, were the Panel to find Mexico's measures inconsistent with one or more of these USMCA provisions, its measures are legally justified under Article 32.1.1 of the UMSCA, which incorporates Article XX of the GATT 1994.[266] Specifically, Mexico invokes subparagraphs (a) and (g) of Article XX, but Mexico's arguments fail in both cases, because the objective sought to be advanced is impermissibly vague; because the measures do not advance the objectives; because other alternatives would advance the objectives to the same or greater degree while being significantly less restrictive to trade; and because the measures constitute arbitrary or unjustifiable discrimination or a disguised restriction on trade. In short, Mexico has not demonstrated it satisfies either the subparagraphs or the chapeau of Article XX.

### A. Analysis under Article XX of the GATT 1994.

197. The United States does not disagree with Mexico that an evaluation under Article XX can proceed using a "two-tier" analysis: first, as to whether the challenged measure falls within the scope of one of the exceptions listed in Article XX(a)-(j); and second, as to whether the measure

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[263] USMCA, art. 24.15.2.

[264] Asociación Nacional de Empresas Comercializadoras de Productores del Campo A.C. Application for Leave to File Written Views (Nov. 6, 2023), at 2.

[265] Revised Panel Decisions on the Applications for Leave to File Written Views, at 2.

[266] Mexico's Initial Submission, para. 486.

satisfies the requirements of the chapeau of Article XX.[267] Mexico must succeed in both respects to establish an exception under Article XX; failure in either respect renders Mexico's defense insufficient to justify its breaches of Article 9.6 and Article 2.11.

198. Article XX is a "general exception" to commitments set out in the WTO Agreement; it provides for certain limited and conditional exceptions to the substantive obligations set forth in the GATT 1994.[268] Because it is an exception to otherwise applicable commitments, it is logical for a responding party to be required to raise a relevant exception as an affirmative defense, and the burden of establishing that an otherwise inconsistent measure satisfies the requirements of one of the exceptions in Article XX would lie with the party invoking the defense.[269] The Rules of Procedure for USMCA accordingly set out that Mexico, as the Party invoking an Article XX exception, bears the burden of proof.[270] The United States will first address in turn Mexico's arguments regarding subparagraphs (a) and (g), and then address the chapeau.

### B. Mexico's Tortilla Corn Ban and Substitution Instruction Are Not Justified by Article XX(a).

199. Mexico asserts that its Tortilla Corn Ban and Substitution Instruction are legally justified because they are "necessary to protect public morals" within the meaning of Article XX(a) of the GATT 1994.[271]

200. Article XX(a) of the GATT 1994 provides in relevant part:

> [N]othing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: (a) necessary to protect public morals[.]

201. Separate from the requirements of the chapeau (addressed below in Section VII.C), a party seeking to establish that a measure is justified under Article XX(a) of the GATT 1994 must

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[267] *See* Mexico's Initial Submission, para. 490; *see also* Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, at 22 (adopted May 20, 1996) (hereinafter "Appellate Body Report, *US – Gasoline*") (Exhibit USA-273).

[268] *General Agreement on Tariffs and Trade 1994* ("GATT 1994"), art. XX (Exhibit USA-298); *see* Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, para. 157 (adopted Nov. 6, 1998) (Exhibit USA-278).

[269] Similar logic has been applied in past WTO reports. *See, e.g.*, Appellate Body Report, *US – Gasoline*, at 22-23 (Exhibit USA-273).

[270] USMCA Rules of Procedure for Chapter 31 (Dispute Settlement), art. 14.2 ("A responding Party asserting that a measure is subject to an exception or affirmative defence under the Agreement has the burden of establishing that the exception or defence applies.").

[271] Mexico's Initial Submission, paras. 491-500.

demonstrate that the measure (i) seeks to protect public morals and (ii) is "necessary" to achieve that objective.[272]

1. Mexico has failed to establish the existence of a valid "public morals" objective.

202. In its Initial Submission, Mexico fails to articulate a "public morals" objective for purposes of Article XX. Mexico asserts that it "has a moral duty to preserve native varieties of corn and the livelihoods of communities that derive their income and livelihood from the cultivation and processing of native varieties and grains."[273] Mexico also cites "seek[ing] to maintain unique gastronomic traditions associated with the use of native varieties of corn.[274]

203. "Public morals" are, in the ordinary sense of these terms, standards relating to right and wrong conduct of the people as a whole. [275] The United States considers that Mexico has scope to define for itself what are "public morals" for its society. However, in light of the status of Article XX(a) as a "general exception," Mexico must identify and explain with precision what are the public morals at issue, and the relation of the measure to those public morals. As a prior WTO panel reasoned, "this latitude [to define its own public morals] does not excuse a responding party in dispute settlement from its burden of establishing that the alleged public policy objective at issue is indeed a public moral objective according to its value system."[276] As the United States discusses below, Mexico does little to explain what it means when it refers to preservation of native corn and seeking to maintain unique gastronomic traditions.

204. But first, the United States notes that preservation of the economic livelihoods of communities does not constitute a public moral. The United States of course recognizes the paramount importance of economic opportunity; indeed, USMCA is designed to enhance economic opportunity for all three parties. But "preservation of livelihoods" is not in itself a standard of good or bad behavior, but a desired economic outcome. Treating it as a public moral would turn Article XX(a) into a sort of economic safeguard, where parties could declare an

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[272] *See, e.g.*, Panel Report, *Colombia – Measures Relating to the Importation of Textiles, Apparel and Footwear*, WT/DS461/R, para. 7.293 (adopted June 22, 2016) ("In the context of Article XX(a), … a Member wishing to justify its measure must demonstrate: (i) that it has adopted or enforced the measure 'to protect public morals,' and (ii) that the measure is 'necessary' to protect such public morals.") (Exhibit USA-274).

[273] Mexico's Initial Submission, para. 494.

[274] Mexico's Initial Submission, para. 494.

[275] "Public," *Oxford English Dictionary*, https://www.oed.com/dictionary/public_adj?tab=meaning_and_use#27758573 ("of or relating to the people as a whole; that belongs to, affects, or concerns the community or the nation") (Exhibit USA-295); "Morals," *Oxford English Dictionary*, https://www.oed.com/dictionary/moral_n?tab=meaning_and_use#36031841 ("a set of personal standards relating to right and wrong conduct") (Exhibit USA-296).

[276] Panel Reports, *Brazil – Certain Measures Concerning Taxation and Charges*, WT/DS472/R, WT/DS497/R, para. 7.558 (adopted Jan. 11, 2019) (hereinafter "Panel Reports, *Brazil – Taxation*") (Exhibit USA-275).

economic threat and then adopt restrictions on imports. This is not the ordinary meaning of "public morals" and not the purpose of this exception.

205. Moreover, Mexico does little to explain what it means by preservation of native varieties of corn. As Mexico acknowledges, corn "is in continuous evolution."[277] Mexico's present-day native corn varieties are a product of ongoing cross-breeding and evolution over millennia, including cross-breeding with non-native hybrids.[278] In fact, Mexico's own policies have encouraged the cultivation and use of hybrids over native varieties.[279] Mexico concedes that "[a]ltering the genetic material of any species will have an effect on the way in which species evolve."[280] Gene flow between corn species is a natural phenomenon that occurs irrespective of whether a corn plant is GE or non-GE,[281] yet Mexico's measures do not prohibit the importation,

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[277] Mexico's Initial Submission, para. 46.

[278] *See, e.g.*, I. Rojas-Barrera et al., "Contemporary Evolution of Maize Landraces and Their Wild Relatives Influenced by Gene Flow with Modern Maize Varieties," 116 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES 21302 (Oct. 2019), https://www.pnas.org/doi/epdf/10.1073/pnas.1817664116 (assessing the adoption of non-GE hybrids and observing introgression (*i.e.*, gene flow) from hybrids into native landraces) (Exhibit USA-166).

[279] *See, e.g.*, "MasAgro Maize," *CIMMYT*, https://masagro.mx/descripcion-general/ (a project of Mexico's Secretariat of Agriculture and Rural Development and CIMMYT, from 2010-2020, which promoted sustainable development through the breeding of maize hybrids with native seed) (Exhibit USA-167); F. D. McLean-Rodríguez et al., "The Abandonment of Maize Landraces Over the Last 50 Years in Morelos, Mexico: a Tracing Study Using a Multi-level Perspective," 36 AGRICULTURE & HUMAN VALUES 651, 653, 655-656 (2019), https://link.springer.com/article/10.1007/s10460-019-09932-3 ("Among the surveyed farmers, the adoption of hybrids was the principal cause for landrace abandonment . . . . In farmers' words, they preferred hybrids over landraces because of their higher yield by weight [and] . . . greater resistance to pests and diseases[.]") (Exhibit USA-168); *id.* at 661 ("[F]armers preferred hybrids because they found them to be more resistant to dry spells and drought than landraces," further explaining that hybrids were more marketable to and favored by tortilla manufacturers) (Exhibit USA-168); *id.* at 662 ("Farmers mentioned they became interested in hybrids after receiving financial subsidies or technological packages from government authorities," noting that "[a]s part of the national strategy for maize self-sufficiency, the Secretary of Agriculture has allocated resources to support hybrid adoption through state governments.") (Exhibit USA-168); *id.* at 664 ("In the municipalities the most common reason for landrace abandonment was the agronomic superiority of the hybrids. However, we found that the preference for hybrids was supported by an entire enabling environment that emerged through the combination of changes in the technological, market, policy and cultural regimes. This enabling environment favored the displacement of landraces by hybrids, other crops, and other economic activities, particularly during the shift from one farmer generation to the next.") (Exhibit USA-168). This article was funded by CGIAR Research Program on MAIZE Agrifood Systems through CIMMYT, which is funded in part by Mexico and the United States, as well as other donors. *See* "Our Funders," *CGIAR & CIMMYT*, https://www.cimmyt.org/about/funders/ (Exhibit USA-169).

[280] Mexico's Initial Submission, para. 137.

[281] As the United States explained in Section IV.B.1, gene flow is a biological process wherein genes from one plant are transferred to another genetically distinct plant through pollen flow. If a transgene is exchanged between plants, it is commonly called "transgene flow." However, the biological processes by which transgene flow occurs (*e.g.*, gene flow from a GE corn variety and a non-GE corn variety) and non-transgene flow occurs (*i.e.*, gene flow

domestic cultivation, or sale of non-GE corn that is not a native variety. Mexico cannot suggest an interest—much less a public moral—in keeping the current DNA of corn varieties in Mexico static.

206. Similarly, Mexico references preventing native corn varieties and gastronomic traditions from being displaced by imports of GE corn and transgenic introgression, but does not explain any more such that the Panel or the United States can understand what exactly the asserted interest and the perceived threat are. According to Mexico's own submission, the corn most commonly used for "direct consumption"—*i.e.*, for dough and tortillas—is white corn, which Mexico contends is imported from the United States in only small volumes because Mexico is otherwise "self-sufficient" in this type of corn.[282]

207. The evidence Mexico marshals to demonstrate that these really are longstanding issues of moral value to Mexico only worsens the problem. Mexico cites a list of 13 laws.[283] It provides a cursory explanation of six of them, and does not even address the others. Of the six it does discuss in footnotes, Mexico refers to:

- The human right to nutritious, sufficient, and quality food;[284]
- The right to health protection and the right to a healthy environment for the development and well-being of people;[285]
- The transfer, handling and use of living modified organisms that may have adverse effects on the conversation of sustainable use of biological diversity; and
- Sustainable development of native corn, boosting the activities of native corn producers, and promoting the biodiversity of native corn.

These are quite different from the preservation of native corn varieties and gastronomic traditions, and Mexico does not elaborate on them to explain how they relate to the stated public morals.

208. The result of Mexico's approach is that already vague public morals are made even less certain. In short, while Mexico has some latitude in defining what are public morals to Mexico,

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between two non-GE varieties) are the same. The manner in which pollen flows from a GE corn plant is no different than how it flows from a non-GE corn plant.

[282] Mexico's Initial Submission, paras. 236-243.

[283] Mexico's Initial Submission, para. 495.

[284] Mexico's Initial Submission, para. 495 n.503.

[285] Mexico's Initial Submission, para. 495 n.505.

its Initial Submission is insufficient in carrying its burden and establishing public morals for the purpose of Article XX(a).[286]

2. Mexico has failed to establish that the measures at issue are "necessary" to protect public morals.

209. Further, the challenged measures at issue are not "necessary" to achieve the objective of protecting Mexico's stated public morals, which on its own defeats Mexico's Article XX(a) defense.

210. The ordinary meaning of "necessary" means "indispensable, vital, essential; requisite."[287] A measure would be indispensable, vital, essential, or requisite to serve an objective (such as to protect public morals) if the objective cannot be achieved without the measure, or there is no other means of achieving the objective. Logically, this also means there must be some rational relationship between the measure and the objective, and a vital contribution to achieving the goal. Prior WTO panels have similarly interpreted the word "necessary" to mean "significantly closer to the pole of 'indispensable' than to the opposite pole of simply 'making a contribution to' [its objective]."[288] Thus, in order for a measure to be "necessary" to protect public morals, a measure must be indispensable, vital, essential, or requisite to achieving the stated objective.

211. In assessing the term "necessary" as used in Article XX of the GATT 1994, WTO panels have relied on the ordinary meaning to pursue an analysis involving four factors: (i) the relative importance of the objective pursued by the measure; (ii) the contribution of the measure to that objective; (iii) the trade-restrictiveness of the measure; and in most cases (iv) the existence of "reasonably available" alternative measures.[289] The United States notes that on this similar approach, Mexico cannot establish that its measures satisfy the last three elements of this analytical framework.

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[286] USMCA Rules of Procedure for Chapter 31 (Dispute Settlement), art. 14.2 ("A responding Party asserting that a measure is subject to an exception or affirmative defence under the Agreement has the burden of establishing that the exception or defence applies").

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

[288] *See, e.g.*, Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, WT/DS169/AB/R, paras. 164-166 (adopted Jan. 10, 2001) (Exhibit USA-120). "Indispensable" has an ordinary meaning of "cannot be dispensed with our done without; absolutely necessary or requisite." "Indispensable," *Oxford English Dictionary*, https://www.oed.com/dictionary/indispensable_adj?tab=meaning_and_use#506312 (Exhibit USA-297).

[289] *See, e.g.*, Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, WT/DS169/AB/R, paras. 164-166 (adopted Jan. 10, 2001) (Exhibit USA-120); Appellate Body Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, WT/DS285/AB/R, paras. 306-307 (adopted Apr. 20, 2005) (Exhibit USA-277).

212. Regarding the second factor, Mexico fails to demonstrate any contribution of the measures to its stated public morals. It provides no evidence of the perceived threat, and no explanation of how the measures would prevent the perceived threat from materializing. Specifically, and setting aside its failure to specifically identify relevant public morals, Mexico has adduced no evidence of a potential threat of GE corn for human consumption dominating the Mexican market, displacing the native corn varieties grown by Mexican farmers, or becoming the corn of choice of cooks of traditional cuisine.

213. Regarding the third factor, and underscoring the previous point, the measures are very trade-restrictive. The Tortilla Corn Ban is maximalist in that it acts as an outright ban. The Substitution Instruction is similarly severe, preventing all GE corn for uses other than dough and tortillas once the phase-in period ends. Moreover, it introduces a massive amount of uncertainty into the market for U.S. farmers, Mexican livestock farmers, commodity markets, biotechnology developers, and Mexican consumers. Even if the phase-in period were long, this would still be a heavily trade-restrictive measure along the spectrum of potential measures.

214. Regarding the fourth factor, Mexico fails to establish the unavailability of alternative measures. Indeed, this is the only factor Mexico actually addresses, and Mexico merely states that "the United States has not proposed any alternatives."[290] Given that Mexico invoked Article XX(a) for the first time in its Initial Submission, the United States would have had no occasion for addressing this factor. Mexico also bears the burden of proof as the party invoking the exception; it is not up to the United States to affirmatively and preemptively establish the existence of alternatives. But, in any event, there are several less trade-restrictive alternatives that Mexico could pursue to address its stated objectives of preventing native corn varieties and gastronomic traditions from being displaced by imports of GM corn and transgenic introgression.

215. Less trade-restrictive alternatives include adapting "co-existence" measures that are employed around the world to mitigate cross-pollination between native and non-native crops, such as spatial isolation and natural barriers; clean equipment and storage measures; continuing or strengthening existing in situ (environment) and ex situ (germplasm banks) conservation measures and adopting new ones; and community outreach and education.[291] Similarly, Mexico's gastronomic traditions are highly regarded and can be served through education, publicity, financial support, gastronomic tourism, and other supply- and demand-enhancing efforts.

216. Thus, Mexico clearly has failed to demonstrate that the heavily trade-restrictive challenged measures are necessary to achieve Mexico's stated public morals objective for purposes of Article XX(a). Accordingly, on this basis alone, Mexico's Article XX(a) defense fails.

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[290] Mexico's Initial Submission, para. 498.

[291] *See supra* Section IV.B.

### C. Mexico's Tortilla Corn Ban and Substitution Instruction Are Not Justified by Article XX(g).

217. Mexico also attempts to justify breaches of the SPS Chapter and Article 2.11 by invoking the exception provided for conservation measures in Article XX(g) of the GATT 1994. However, for the reasons discussed in the following sections, Mexico has failed to establish that its measures meet the requirements of that exception. Specifically, Mexico (i) fails to demonstrate that the Tortilla Corn Ban and the Substitution Instruction relate to the conservation of exhaustible natural resources, and (ii) further fails to demonstrate that either measure is made effective in conjunction with restrictions on domestic production or consumption. Each of these failures alone is an independent basis for rejecting Mexico's Article XX(g) defense.

218. GATT Article XX(g) provides an exception from the requirements of the GATT 1994 for measures:

> relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption.

In order to be provisionally justified under Article XX(g), Mexico must demonstrate that the Tortilla Corn Ban and the Substitution Instruction: (i) relate to the conservation of exhaustible natural resources and (ii) are made effective in conjunction with restrictions on domestic production or consumption.

#### 1. Mexico's Tortilla Corn Ban and Substitution Instruction are not "relating to" the conservation of an exhaustible natural resource.

219. First, Mexico notes that its native varieties are "exhaustible natural resources" *because* they are "under threat of loss and possibly extinction as evidenced through the transgenic contamination of native corn in Mexico."[292] Mexico draws the conclusion that these natural resources are "exhaustible" by relying on a single study that found the presence of introgressed transgenic DNA constructs in native maize landraces grown in Oaxaca, Mexico.[293] And it ignores the overwhelming weight of the evidence supporting the opposite conclusion.[294]

220. As the United States explained in Section IV.A.3.c, Mexico's own government agencies have testified in a court of law that there is no evidence of unauthorized release of GE corn seeds

[292] Mexico's Initial Submission, para. 507.

[293] Mexico's Initial Submission, para. 507 (citing MEX-090).

[294] *See, e.g.*, *supra* Sections IV.A.3.c; IV.B.

licensed for cultivation (let alone GE corn grain imported for food and feed uses), and have no evidence of any adverse effects to native corn varieties.[295]

221. In the relevant collective action evaluating these very issues, the Mexican federal court recently concluded that accidental or involuntary release of GE corn seed was "unfounded," and even if such releases had occurred, that "does not mean that there is an impairment or damage to the biological diversity of native corn," observing that there are remediation procedures under the Biosafety Law to regulate and sanction unauthorized behavior.[296] The court went even further to state that, *even if* there were no remediation procedures available under Mexico's Biosafety Law:[297]

> [T]his does not imply in any way that the accidental or involuntary release of genetically modified corn, if any, necessarily entails the extinction of native corn, or that it irreparably affects the biological diversity of such native corn, since its conservation is fully guaranteed both in situ (environment) and ex situ (germplasm banks).

222. The court firmly rejected the collective's claims that GE corn grain could negatively impact Mexico's native corn varieties and reaffirmed their ability to coexist, whether the GE corn grain were cultivated or imported for food and feed use.[298]

223. Furthermore, the measure does not bear the necessary relationship to the asserted exhaustible natural resource—native corn. For a measure to "relate to" conservation, it must bear a relationship to the goal of conservation. Past WTO reports have described this relationship as "a close and genuine relationship of ends and means"[299] which requires an examination of the relationship between the general structure and design of a measure and the policy goal it purports to serve—*i.e.*, the conservation of its native varieties.

224. Putting aside the lack of evidence of an actual threat, and taking Mexico at its word, the risk logically would be from *non-native corn*, not just GE corn. Mexico does not explain how any gene flow from GE corn necessarily affects the biodiversity and genetic integrity of

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[295] Judicial Branch of the Federation of the United Mexican States, Final Judgment 321/2013-I (Sept. 28, 2023) (English excerpt) (Exhibit USA-165).

[296] *Id.* at 3, 5 (Exhibit USA-165).

[297] *Id.* at 5-6 ("Also in this Global Native Corn Project, the biological diversity of native corn in the national territory is guaranteed, as a great diversity of originally registered native breeds has been found, and the in situ and ex situ conservation of the biological diversity of these corn varieties is fully guaranteed.") (Exhibit USA-165); *id.* at 6 ("The foregoing, added to the fact that native corns in our national territory have been produced and consumed in a constant and uninterrupted way, so that in no way is the sustainable use of native corns threatened, clearly defined in the Convention on Biological Diversity of 1992 . . . .") (Exhibit USA-165).

[298] *Id.* at 6-7 (Exhibit USA-165).

[299] *See, e.g.,* Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, para. 135 (adopted Nov. 6, 1998) (Exhibit USA-278).

Mexico's native varieties in a manner different from, or any more negatively, than gene flow from non-native, non-GE corn varieties or cross-breeding between native varieties. Any conservation measures aimed at preventing Mexico's stated concern—the genetic integrity of native corn[300]—would need to address any gene flow that introduces "non-native" genes.

225. Thus, Mexico's measures do not, for purposes of Article XX(g), "relate to" the conservation of the exhaustible natural resource Mexico identified. Accordingly, Mexico's attempted reliance on the Article XX(g) exception fails.

2. Mexico's Tortilla Corn Ban and Substitution Instruction are not made effective in conjunction with restrictions on domestic production or consumption.

226. In order for a measure to be justified under Article XX(g), the measure must also be "made effective in conjunction with restrictions on domestic production or consumption." This second clause of Article XX(g) requires that there *exist* "restrictions on domestic production or consumption" and that the measure at issue be "made effective in conjunction with" such restrictions. This serves as an independent basis for rejecting Mexico's Article XX(g) defense without regard to the insufficiency in fulfilling the first clause (*i.e.*, "relating to").

227. The requirement that there exist restrictions on domestic production or consumption ensures that the burden of conserving the exhaustible natural resource is not put solely or predominantly on imports. That is, restrictions must be applied both to imports via the challenged measure and also to domestic production or consumption. The WTO dispute settlement report in *U.S. – Gasoline* interpreted the second clause of Article XX(g) to be a "requirement of even-handedness in the imposition of restrictions, in the name of conservation, upon the production or consumption of exhaustible natural resources."[301] The report noted that, while there is "no textual basis for requiring identical treatment of domestic and imported products . . . if no restrictions on domestically-produced like products are imposed at all, and all limitations are placed upon imported products alone, the measure cannot be accepted as primarily or even substantially designed for implementing conservationist goals."[302]

228. Here, Mexico cites the moratorium on cultivation of GE corn in Mexico as well as the restrictions on glyphosate in Articles 3, 4, and 5 of the 2023 Corn Decree.

229. As an initial matter, the United States is not challenging Articles 3 through 5 of the 2023 Corn Decree.

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[300] Mexico's Initial Submission, paras. 506-507.

[301] Appellate Body Report, *US – Gasoline*, at 21 (Exhibit USA-273).

[302] *Id*. (Exhibit USA-273).

230. And while Mexico cites the moratorium as evidence of even-handedness vis-à-vis GE corn, it actually is evidence of the opposite in the context of the exhaustible natural resource Mexico has put forward—protection of "native corn." Again putting aside the lack of evidence of an actual threat, and taking Mexico at its word, the risk logically would be from non-native corn, not just GE corn. By imposing trade restrictions only on GE corn, but not imposing restrictions on "non-native" non-GE corn in Mexico, the burden of Mexico's challenged measures falls solely on imports.

231. This runs afoul of Article XX(g)'s requirement that, if restrictions are imposed on imports to preserve exhaustible natural resources, they must be made effective in conjunction with restriction on domestic production or consumption too. Put differently, because no real restrictions on domestic production and consumption are imposed at all, and all limitations are placed upon imported products alone, the challenged measures do not appear designed to conserve a natural resource.

232. Furthermore, the single piece of evidence Mexico does cite is for the proposition that "[t]here is evidence that clandestine and illegal cultivation of GM corn has been happening in Mexico."[303] Again putting aside for the moment that the weight of the evidence does not support this conclusion, if this really were a concern, it is difficult to see how another law precluding the already-forbidden activity would address the problem. That this inapt solution happens to impact only imports underscores that these measures are not designed to conserve exhaustible natural resources.

### D. Even if a Challenged Measure Were Preliminarily Justified Under an Article XX Subparagraph, All of the Challenged Measures Are Applied Inconsistently with the Article XX Chapeau.

233. As discussed in Section VII.A, Mexico—as the party invoking an Article XX exception—has the burden to demonstrate that it has met the requirements of the chapeau of Article XX. That is, Mexico must demonstrate that each measure at issue is not (i) applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or (ii) a disguised restriction on international trade. Mexico's arguments fail because Mexico has not shown that its measures are not used as a disguised restriction on trade or a means of arbitrary or unjustified discrimination within the meaning of the first clause of this provision.

#### 1. Mexico Has Not Established that Its Tortilla Corn Ban and Substitution Instruction are Not a Disguised Restriction on International Trade.

234. Mexico's Initial Submission fails to demonstrate how the Tortilla Corn Ban and Substitution Instruction are not disguised restrictions on international trade, a required element

[303] Mexico's Initial Submission, para. 509.

for a measure to be exempted under the chapeau of Article XX, and therefore a requirement to satisfy any of the exceptions in the Article XX sub-paragraphs. Mexico does not attempt to argue that its measures do not constitute a disguised restriction on international trade, and instead only addresses whether the challenged measures constitute arbitrary or unjustifiable discrimination.[304]

235. Although Mexico bears the burden of proof in this instance, the United States observes that the measures do constitute disguised restrictions on trade. The face of the measure and Mexico's comments publicly and in its Initial Submission describe these measures as predominantly driven by concerns over human and plant health and, to a lesser extent, cultural traditions. But the design and context of the measures, along with other public statements, reveal the otherwise disguised intent to restrict international trade.

236. First, there is the poor fit between the measures and their ostensible purpose. As has been covered at length elsewhere in this submission,[305] Mexico abruptly abandoned the accepted science based on international standards for no science-based reason. Indeed, procedurally, Mexico did not pursue the types of actions one would expect (and the USMCA requires) if there were a legitimate scientific inquiry, such as a risk assessment. The evidence is no more supportive on the plant health side, where Mexico has not even clearly explained the risk it supposedly is addressing, with a theory and supporting evidence for how the measure would address such a risk.[306] This is especially glaring given that GE corn has been imported into Mexico for decades with no documented harms that reflect the allegedly severe outcomes Mexico now contemplates. Furthermore, Mexico does not explain how the supposed risks to plant health would justify the continued importation of GE corn until such time as the Substitution Instruction is fully implemented. Were Mexico pursuing its stated objectives in earnest, the measures' design and the factual evidence would look very different than what is before the Panel.

237. Second, Mexico has made isolated statements that reveal the intent to restrict trade. There are references in the 2023 Corn Decree as well as in Mexico's Initial Submission to "self-sufficiency," which implies a preference for buying domestic production at the expense of supply that is currently imported.[307] In addition, Mexico asserts in its Initial Submission that the Tortilla Corn Ban "will play an important role in safeguarding both local production and gastronomic heritage from being overtaken by the preferred U.S. production methodology."[308] Given that "the preferred U..S production methodology" here refers to GE crops that Mexico has already

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[304] *See* Mexico's Initial Submission, paras. 518-526.

[305] *See, e.g., supra* Sections IV.A, IV.E.

[306] *See, e.g., supra* Sections IV.A, IV.B, IV.F.

[307] *See, e.g.*, 2023 Corn Decree, preamble (Exhibit USA-3); *id.*, art. 8 (Exhibit USA-3); Mexico's Initial Submission, paras. 216, 284.

[308] Mexico's Initial Submission, para. 499.

banned for cultivation in Mexico, this phrase really refers merely to U.S. (and potentially other imported) corn.

238. Furthermore, Mexico states that it has a "duty to preserve . . . the livelihoods of communities that derive their income and livelihood from the cultivation and processing of native varieties of grains."[309] That is another way of saying to protect Mexican producers in competition with imported corn. This is reinforced by the fact that Mexico did not adopt a measure that requires, supports, or encourages a certain amount of planting of these native varieties. Nor, even under a flawed theory of how transgenes and cross-pollination work,[310] did Mexico discipline non-native corn varieties (whether GE or not). Instead, Mexico's measures target GE corn, which is only from foreign sources.

239. Third, the effect of these measures suggests a clear targeting of imports. As has been discussed previously,[311] Mexico banned the cultivation of GE corn in Mexico in 2013. Thus, by imposing measures that target GE corn, and not any "non-native" corn, Mexico only impacts imports of corn, to the benefit of domestic producers that plant non-GE corn.

240. From the text of Mexico's bans, the structure of those measures, and relevant public statements, it appears that Mexico's objective is to import corn only to the extent necessary, and then not at all when imports are no longer necessary. The measures are thus disguised restrictions on trade, under the guise of measures intended to protect human or plant health, or other objectives. As a result, Mexico's attempt to invoke the exceptions in GATT 1994 Article XX fails, which in turn prevents successful invocation of USMCA Article 32.1.

### 2. Mexico Has Not Established That Its Tortilla Corn Ban and Substitution Instruction Do Not Constitute Arbitrary or Unjustifiable Discrimination.

241. Mexico's failure to establish that its measures are not a disguised restriction on trade, and the demonstration above that they are disguised restrictions, ends the Article XX analysis as each element of the chapeau must be met for a measure to be justified. For completeness, the United States notes that Mexico does put forward an analysis on whether its measures constitute arbitrary or unjustifiable discrimination,[312] but its arguments in this respect are unavailing. Mexico relies on the approach taken by WTO reports, which looks at the three elements present in the language of the Article XX chapeau: (i) the application of the measure must result in discrimination; (ii) the discrimination must occur between countries where the same conditions

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[309] Mexico's Initial Submission, para. 494.

[310] *See supra* Section IV.B.1 (explaining why, as a scientific matter, transgene flow from imported GE corn intended for food or feed use is unlikely).

[311] *See supra* Section IV.A.3.c.

[312] *See* Mexico's Initial Submission, paras. 518-526.

prevail; and (iii) the discrimination must be arbitrary or unjustifiable in character.[313] Mexico's arguments fail for much the same reasons that it fails to show its measures are not a disguised restriction on trade.

242. Mexico's measures do result in discrimination between countries where the same conditions prevail that is arbitrary or unjustifiable. The United States has previously addressed the ways in which the challenged measures unduly target imports. By imposing trade restrictions only on GE corn, but not imposing restrictions on "non-native" non-GE corn in Mexico, and in light of the moratorium on cultivation of GE corn in Mexico, Mexico designed measures that simultaneously depart from the stated objective of protecting native corn and shift the entirety of the challenged measures' burden onto imports. There is no basis in Mexico's stated policy objectives for this different and detrimental treatment of imported corn as compared to domestic corn.

243. Accordingly, Mexico's failure to demonstrate that its measures do not arbitrarily and unjustifiably discriminate between countries where the same conditions prevail provides an additional, independent basis to reject Mexico's Article XX defenses.

## VIII. MEXICO HAS FAILED TO DISCHARGE ITS BURDEN OF ESTABLISHING THAT USMCA ARTICLE 32.5 APPLIES.

244. As with the other affirmative defenses it attempts to invoke, Mexico has failed to discharge its burden of establishing that Article 32.5 of the USMCA justifies its measures.[314] Article 32.5 states:

> Provided that such measures are not used as a means of arbitrary or unjustified discrimination against persons of the other Parties or as a disguised restriction on trade in goods, services, and investment, this Agreement does not preclude a Party from adopting or maintaining a measure it deems necessary to fulfill its legal obligations to indigenous peoples.[315]

Mexico's arguments fail, because Mexico has not shown that its measures are not used as a disguised restriction on trade in goods or a means of arbitrary or unjustified discrimination within the meaning of the first clause of this provision.

245. The phrase "disguised restriction on trade in goods, services and investment" in Article 32.5 is very similar, though not identical, to the phrase "disguised restrictions on international

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[313] Mexico's Initial Submission, para. 518 (citing Appellate Body Report, *US – Shrimp*, para. 150).

[314] USMCA Rules of Procedure for Chapter 31 (Dispute Settlement), art. 14.2 ("A responding Party asserting that a measure is subject to an exception or affirmative defence under the Agreement has the burden of establishing that the exception or defence applies").

[315] USMCA, art. 32.5.

trade" in the chapeau of GATT 1994 Article XX. Similarly, the phrase "arbitrary or unjustified discrimination against persons of the other Parties" in Article 32.5 is very similar, though not identical, to the phrase "arbitrary or unjustifiable discrimination between countries where the same conditions prevail" in the chapeau of GATT 1994 Article XX. The differences in language do not have significance to the issues currently before the Panel.

246. Therefore, the United States will not repeat its arguments already proffered in the context of the chapeau of GATT 1994 Article XX in Section VII.D above. Instead, the United States incorporates those arguments by reference here in the context of USMCA Article 32.5. Mexico's bans do constitute a disguised restriction on trade and arbitrary or unjustified discrimination because they are designed and applied to restrict imports of GE corn while not affecting domestic production of non-native, non-GE corn, thus uniquely disadvantaging U.S. exports, and because they do not serve to accomplish Mexico's asserted objectives.

247. Mexico also argues that, because the United States has not alleged a breach of USMCA national treatment obligations in this dispute, and because the measure does not expressly discriminate against "persons," the measure cannot constitute a means of arbitrary or unjustified discrimination under Article 32.5.[316] Contrary to Mexico's assertions, "discrimination" for the purposes of Article 32.5 does not refer to the same standard by which a breach of any substantive rule of the USMCA is determined, much less require that a formal national treatment claim have been brought in the same dispute. Such an argument would suggest that a respondent could almost ensure the success of an Article 32.5 defense anytime a dispute is brought that does not include a national treatment claim. If such an automatic effect were intended, that could have been made clear in the text. It was not.

248. Definitions of "discrimination" include not only "[t]he treatment of goods, trading partners, etc., on a more or less favourable basis according to circumstances," but also "[t]he action of perceiving, noting, or making a distinction between things."[317] Thus, Mexico cannot evade the requirements of Article 32.5 by simply noting that the United States has not alleged in this dispute a breach of a particular USMCA national treatment obligation. Instead, Mexico must establish that its measures do not make a distinction between things or treat its trading partners on a less favorable basis according to circumstances.

249. Mexico's cursory arguments also ignore the broad definition of the term "person" in USMCA, to include not only natural persons, but also enterprises.[318] And an enterprise, in turn, is defined as "an entity constituted or organized under applicable law, whether or not for profit, and whether privately-owned or governmentally-owned or controlled, including a corporation, trust, partnership, sole proprietorship, joint venture, association or similar organization." In light

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[316] Mexico's Initial Submission, para. 531.

[317] "Discrimination," *Oxford English Dictionary*, https://www.oed.com/dictionary/discrimination_n?tab=meaning_and_use#6527704 (Exhibit USA-283).

[318] USMCA, art. 1.5.

of this broad definition, Mexico must show that its measures are not used as a means of arbitrary or unjustified discrimination against not only natural persons of other Parties, but also entities constituted or organized under U.S. law, including U.S. exporters. Mexico has not even attempted to make this showing.

250. As a result, and for the reasons incorporated by reference, Mexico has failed to establish that the challenged measures are not used as a means of arbitrary or unjustified discrimination against persons of the other Parties or as a disguised restriction on trade in goods, services, and investment. Accordingly, and without further analysis of the rest of Article 32.5, Mexico's attempt to invoke that provision fails.

## IX. ALTERNATIVELY, A BENEFIT THE UNITED STATES REASONABLY COULD HAVE EXPECTED TO ACCRUE TO IT UNDER USMCA IS BEING NULLIFIED OR IMPAIRED AS A RESULT OF THE APPLICATION OF MEXICO'S MEASURES.

251. Should the Panel find—contrary to the U.S. arguments above—that the Tortilla Corn Ban or the Substitution Instruction are not inconsistent with Mexico's USMCA obligations due to the applicability of the indigenous peoples' exception in USMCA Article 32.5, the United States alternatively asserts that it had a reasonable expectation at the time the USMCA was concluded that Mexico would not adopt the Tortilla Corn Ban or the 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 each measure. The United States would therefore ask the Panel to determine pursuant to Article 31.13.1(b)(iii) that these measures are causing nullification or impairment within the meaning of Article 31.2(c).[319]

252. As Article 31.2 provides in relevant part:

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[319] *See* U.S. Panel Request, para. 1, n.5 ("Alternatively, pursuant to USMCA Article 31.2(c), the United States asserts that it had a reasonable expectation at the time the USMCA was concluded that Mexico would not adopt the Tortilla Corn Ban. 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."); U.S. Panel Request, para. 2, n.9 ("Alternatively, pursuant to USMCA Article 31.2(c), the United States asserts that it had a reasonable expectation at the time the USMCA was concluded that Mexico would not adopt the 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."); *see also* U.S. Initial Submission, para. 67, n.136 ("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 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.").

> Unless otherwise provided for in this Agreement, the dispute settlement provisions of this Chapter apply:
>
> (c) when a Party considers that a benefit it could reasonably have expected to accrue to it under Chapter 2 (National Treatment and Market Access for Goods) . . . [or] Chapter 9 (Sanitary and Phytosanitary Measures) . . . , is being nullified or impaired as a result of the application of a measure of another Party that is not inconsistent with this Agreement.

253. As the United States has established, the Tortilla Corn Ban constitutes an immediate ban on GE corn for nixtamalization or flour production, while the Substitution Instruction instructs Mexican authorities to gradually substitute GE corn used for animal feed and for human consumption other than in nixtamalization or flour production. These measures are undoubtedly being applied,[320] and even in the case that they were found to be not inconsistent with USMCA—despite the U.S. demonstration to the contrary—the United States had a reasonable expectation at the time the USMCA was concluded that trade in GE corn would continue as it had for years. Put differently, the U.S. expectation that it would continue to be able to export its top agricultural product to Mexico was reasonable because Mexico had not indicated that it would adopt these measures intended to completely stop those exports. Accordingly, a benefit that the United States could reasonably have expected to accrue to it under Chapter 2 or Chapter 9 is being nullified or impaired as a result of the application of these measures.

### A. The United States Reasonably Could Have Expected to Accrue Benefits Under Chapter 2 and Chapter 9.

254. The ordinary meaning of the terms in the phrase "a benefit that [a Party] could reasonably have expected to accrue" is broad. Dictionary definitions of "benefit" include "[a]dvantage, profit, good", as well as "[a] natural advantage or 'gift,'"[321] while "reasonably" may be defined as "[a]ccording to reason; with good reason, legitimately; justly, properly, fairly."[322] Thus, a "benefit" the United States "could reasonably have expected to accrue" could be understood as an advantage (including a natural advantage) or good that the United States legitimately or fairly could have expected.

255. U.S. exports of corn have long moved freely to Mexico, and—until recently—Mexico facilitated this access, including for GE corn. While the North American Free Trade Agreement ("NAFTA") permitted Mexico to regulate U.S. access to its corn market via a tariff-rate quota until 2007, Mexico opted to open its markets to U.S. corn more than the NAFTA required,

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[320] *See supra* Section III.A.

[321] "Benefit," *Oxford English Dictionary*, https://www.oed.com/dictionary/benefit_n?tab=meaning_and_use#23477390 (Exhibit USA-280).

[322] "Reasonably," *Oxford English Dictionary*, https://www.oed.com/dictionary/reasonably_adv?tab=meaning_and_use#26491920 (Exhibit USA-284).

particularly during the latter years of this transition.[323] Beginning in 2008, the NAFTA lifted all formal restrictions, allowing U.S. corn to enter Mexico free of all tariffs and quotas.[324] Thereafter, U.S. exports to Mexico of corn and corn-based products blossomed, and according to USDA, U.S. exports of white corn and yellow corn rose from less than 190 million dollars in 1994 to more than $3 billion dollars in 2018.[325] The USMCA continued this tariff-free and quota-free trade in corn,[326] and in 2022—when GE products accounted for over 93 percent of corn planted in the United States—the United States exported more than $4 billion in corn to Mexico.[327]

256. As this prior trade suggests, Mexico permitted the importation and sale of GE corn for decades, and has been one of the countries with the most authorizations for importing and selling GE crops for use in human food and animal feed. As discussed in Section II.D of the U.S. Initial Submission, Mexico's principal legal instruments governing the importation and sale of agricultural biotechnology products in Mexico date from 2005, and in the years following the promulgation of these instruments Mexico regularly reviewed and approved authorization applications for GE events for food and feed use in Mexico.[328] During this time Mexico issued over 200 event authorizations across 11 different GE crops—and the number of authorizations

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[323] *See* Steven Zahniser, Nicolás Fernando López López, Mesbah Motamed, Zully Yazmin Silva Vargas, and Tom Capehart, *The Growing Corn Economies of Mexico and the United States*, United States Department of Agriculture, FDS-19F-01, at 3 (Aug. 2019), https://www.ers.usda.gov/webdocs/outlooks/93633/fds-19f-01.pdf?v=5103#:~:text=most%20significantly%2C%20Mexico.-,Since%20the%20start%20of%202008%2C%20U.S.%20corn%20exports%20to%20Mexico,as%20livestock%20and%20poultry%20feed (Exhibit USA-285).

[324] *Id.* (Exhibit USA-285).

[325] *See id.* (Exhibit USA-285).

[326] *See, e.g.*, USMCA, art. 2.4.2 ("Unless otherwise provided in this Agreement, each Party shall apply a customs duty on an originating good in accordance with its Schedule to Annex 2-B (Tariff Commitments)."); USMCA Annex 2-B, para. 1 ("The rate of customs duty for an originating good under this Agreement is indicated in each Party's Schedule to this Annex."); USMCA, Annex 2-B, para. 2 ("Except as otherwise provided in a Party's Schedule to this Annex, and in accordance with Article 2.4 (Treatment of Customs Duties), the rate of customs duty on originating goods is designated with '0,' and these goods shall be duty-free on the date of entry into force of this Agreement."); USMCA Tariff Schedule of Mexico, https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/MX_Tariff_Schedule.pdf (listing "0" for all HTS Code 1005: Corn (maize) entries) (Exhibit USA-286); Steven Zahniser, Nicolás Fernando López López, Mesbah Motamed, Zully Yazmin Silva Vargas, and Tom Capehart, *The Growing Corn Economies of Mexico and the United States*, United States Department of Agriculture, FDS-19F-01, at 3-4 (Aug. 2019), https://www.ers.usda.gov/webdocs/outlooks/93633/fds-19f-01.pdf?v=5103#:~:text=most%20significantly%2C%20Mexico.-,Since%20the%20start%20of%202008%2C%20U.S.%20corn%20exports%20to%20Mexico,as%20livestock%20and%20poultry%20feed (Exhibit USA-285).

[327] *See* U.S. Initial Submission, para. 6.

[328] *See* U.S. Initial Submission, paras. 42, 50.

for corn alone nearly equals the number of authorizations for the other ten GE crops combined.[329] In fact, prior to its sudden, recent reversal of policy, Mexico repeatedly touted the benefits of biotechnology, for example, noting that biotechnology can solve agricultural problems quickly and with minimal risk, meet critical food and healthcare needs, and contribute to sustainable development.[330]

257. In negotiating what became the USMCA, the United States, Mexico, and Canada sought an ambitious outcome that would update the NAFTA and generate important economic opportunities for all three countries.[331] After the USMCA entered into force, Mexico called the USMCA one of the most ambitious instruments it had negotiated on SPS matters,[332] and noted that the USMCA SPS provisions improved disciplines provided for in the WTO SPS Agreement.[333] Notably, Mexico also described the USMCA SPS Chapter as ensuring the

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[329] *See* U.S. Initial Submission, paras. 2, 51.

[330] *See*, *e.g.*, CIBIOGEM, Informe Annual de la Situación General Sobre la Bioseguridad en México (2015), at 6, https://conahcyt.mx/cibiogem/images/cibiogem/sistema_nacional/informes/Informe-Anual-Sobre-la-Bioseguridad-2015.docx (observing that the applications of biotechnology are innumerable in agriculture, given the large number of problems facing the agricultural industry and that plant biotechnology represents a tool to solve agricultural problems in less time and with minimal risk as a clean technology, where the only characteristic that is to be counteracted is modified, achieving results quickly in a single generation) (Exhibit USA-287); CIBIOGEM, Informe Annual de la Situación General Sobre la Bioseguridad en México (2017), at 6, https://conahcyt.mx/cibiogem/images/cibiogem/sistema_nacional/informes/Informe-Anual-Sobre-la-Bioseguridad-2017.pdf (stating that modern biotechnology has great potential to promote the well-being of humanity, particularly in meeting critical needs in food, agriculture and healthcare) (Exhibit USA-288); CIBIOGEM and CONACYT, OGMs, at 2, https://conahcyt.mx/cibiogem/images/cibiogem/comunicacion/divulgacion/OGM-3082018-web.pdf (acknowledging that to date no GEs consumed have caused health problems and that various organizations recognize that modern biotechnology can contribute to the sustainable development and/or solve challenges presented by climate change) (Exhibit USA-289).

[331] *See*, *e.g.*, Trilateral Statement on the Conclusion of NAFTA Round One (Aug, 20, 2017), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2017/august/trilateral-statement-conclusion#:~:text=While%20a%20great%20deal%20of,the%20benefit%20of%20our%20citizens and Declaración Trilateral sobre la conclusión de la Primera Ronda de Negociaciones del Tratado de Libre Comercio de América del Norte (Aug. 20, 2017), https://www.gob.mx/se/articulos/declaracion-trilateral-sobre-la-conclusion-de-la-primera-ronda-de-negociaciones-del-tratado-de-libre-comercio-de-america-del-norte-122167?idiom=es (Exhibit USA-290); Trilateral Statement on the Conclusion of the Second Round of NAFTA Negotiations (Sep. 5, 2017), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2017/september/trilateral-statement-conclusion-0 and Declaración Trilateral sobre la Conclusión de la Segunda Ronda de Negociaciones del TLCAN (Sep. 5, 2017), https://www.gob.mx/se/articulos/declaracion-trilateral-sobre-la-conclusion-de-la-segunda-ronda-de-negociaciones-del-tlcan-125404?idiom=es (Exhibit USA-291).

[332] Economía, Medidas Sanitarias y Fitosanitarias, Seminario T-MEC – TIPAT, at 17 (Feb. 26, 2020), https://www.gob.mx/cms/uploads/attachment/file/536920/3sesion3PresentacionMedidasSanitariasFitosanitariasSeminarioTMECTIPAT_RAG_.pdf (Exhibit USA-292).

[333] Economía, Resumen del Tratado de Libre Comercio México-Estados Unidos-Canadá, at 3 (June 5, 2019), https://comisiones.senado.gob.mx/puntos_constitucionales/docs/TMEC/resumen_SE_050619.pdf (Exhibit USA-293).

protection of life and health and with the aim to advance decision-making with a scientific basis and to avoid unnecessary obstacles to trade.[334] With respect to the National Treatment and Market Access Chapter, Mexico noted that its purpose was to provide greater certainty and transparency to the commercial exchange of goods between the USMCA parties, in order to facilitate and promote trade in North America.[335]

258. The history of Mexico's actions in the period leading to the successful renegotiation of the NAFTA supports the reasonableness of the U.S. expectation. Mexico permitted the importation and sale of corn, including GE corn, for decades before the USMCA entered into force. Mexico itself touted the benefits of GE corn as well as its safety, authorizing numerous GE events. Mexico also encouraged the tariff-free and quota-free entry of that GE corn. Mexico further lauded the ambition of the USMCA outcomes on SPS and market access. Accordingly, it was reasonable for the United States to expect that Mexico would not completely reverse itself by banning the use of GE corn in dough and tortillas and instructing Mexican government agencies to gradually substitute the use of GE corn in all products for human consumption and for animal feed. Instead, the United States could—and did—reasonably expect that the volume and value of U.S. exports to Mexico of corn, including GE corn, would continue under Chapter 2 and Chapter 9 after USMCA entered into force.

### B. The Measures at Issue are Causing Nullification or Impairment Within the Meaning of Article 31.2.

259. The Tortilla Corn Ban and the Substitution Instruction are causing nullification or impairment within the meaning of Article 31.2. As described in Section II.A. of the U.S. Initial Submission and in Section IX.A above, U.S. exports of corn have long moved freely to Mexico, with the United States exporting $4.9 billion in corn to Mexico in 2022. In that year, GE products accounted for over 93 percent of corn planted in the United States,[336] and the United States is also the largest producer of GE crops in the world.[337] 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.[338] Accordingly, the Tortilla Corn Ban and the Substitution Instruction are causing significant nullification or impairment within the meaning of Article 31.2.

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[334] Economía, Preguntas Frecuentes Sobre El Capitulado Del T-MEC, at 6, https://www.gob.mx/cms/uploads/attachment/file/616504/T-MEC_preguntas_frecuentes-20210216_a.pdf (Exhibit USA-294).

[335] Economía, Preguntas Frecuentes Sobre El Capitulado Del T-MEC, at 2-3, https://www.gob.mx/cms/uploads/attachment/file/616504/T-MEC_preguntas_frecuentes-20210216_a.pdf (Exhibit USA-294).

[336] *See* U.S. Initial Submission, para. 6.

[337] *See* U.S. Initial Submission, para. 7.

[338] *See* U.S. Initial Submission, para. 6.

260. The Tortilla Corn Ban and the Substitution Instruction are already having significant impacts on current trade, as explained in Section II.C above, by making it illegal to import GE corn for use in dough and tortillas and by ordering the phasing out of imported GE corn for other uses. In the eleven months following the enactment of the 2023 Corn Decree (the latest data available), U.S. white corn exports to Mexico, by volume, have collapsed, falling by approximately 40 percent year-on-year and by 50 percent in total value as a result of Mexico's restrictions on the use of GE corn.[339]

261. The Substitution Instruction has also created significant uncertainty for U.S. farmers and companies as well as Mexican importers and food producers. U.S. farmers and companies are unable to plan for upcoming growing seasons, as they cannot begin growing or commercializing a new GE product until it is evaluated and can be lawfully marketed, including in key U.S. export markets such as Mexico.[340] U.S. and Mexican businesses are negatively affected in their business plans and commercial relationships as a result of the uncertain market access for U.S. yellow corn. Furthermore, by instructing 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 animal feed—the Substitution Instruction makes clear that once the substitution is carried out, there will be no permissible uses for GE corn under Mexico's authorization regime.

262. In sum, as indicated by the significant drops in U.S. white corn exports to Mexico, the inability of U.S. companies and farmers to plan their business and agricultural futures, and the $4.9 billion of corn that the United States exported to Mexico in 2022, the Tortilla Corn Ban and the Substitution Instruction are causing significant nullification or impairment within the meaning of Article 31.2.

263. Accordingly, should the Panel find—contrary to the U.S. arguments above—that the Tortilla Corn Ban or the Substitution Instruction is not inconsistent with Mexico's USMCA obligations due to the applicability of the indigenous peoples' exception in USMCA Article 32.5, the United States respectfully requests the Panel to determine pursuant to Article 31.13.1(b)(iii) that these measures are causing nullification or impairment within the meaning of Article 31.2(c).

## X. CONCLUSION

For all the reasons set forth above and in the Initial Written Submission of the United States in this dispute, the United States respectfully requests that this Panel find that Mexico's measures covered in the U.S. panel request are inconsistent with Mexico's commitments under the USMCA.

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[339] U.S. Census Bureau Data, "U.S. Corn Exports to Mexico 2022-Jan. 2024" (Exhibit USA-229).

[340] *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).

**ANNEX I - ASSESSMENT OF ARTICLES CITED IN MEXICO'S INITIAL SUBMISSION CONCERNING ALLEGED ADVERSE HUMAN HEALTH EFFECTS FROM CONSUMING GE CORN[1]**

| PARAGRAPH | EXHBIT | SOURCE TITLE | ANALYSIS |
|---|---|---|---|
| 130 | MEX-118 | Bernstein IL, Bernstein JA, Miller M, Tierzieva S, Bernstein DI, Lummus Z, Selgrade MK, Doerfler DL, Seligy VL. "*Immune responses in farm workers after exposure to Bacillus thuringiensis pesticides. Environ Health Perspect."* | This is a study of applicators of *Bt* sprays, not exposure to transgenic plants. This study is not relevant to *Bt* exposure through transgenic crops or food. |
| 132 | MEX-126 | Séralini GE, Cellier D, de Vendomois JS. "*New analysis of a rat feeding study with a genetically modified maize reveals signs of* | This is just a statistical re-analysis of data from a biotechnology developer. This particular study is a whole-food animal feeding study, which is known to be difficult to interpret. Because these studies are so difficult to interpret, a comparative approach to safety assessment is used to specifically avoid having to rely on these kinds of studies.[2] This comparative approach is laid out in the |

[1] To the extent the United States has not commented on a particular exhibit cited by Mexico in its Initial Submission, such an omission should not be interpreted as endorsement of the exhibit's credibility or relevance.

[2] In fact, directly responding to Séralini's work, the EU has dedicated three (multi-million euro) special projects to evaluate the need for such studies, and all three found that such studies were not ordinarily likely to provide useful information and did not meaningfully improve safety assessments for crops with agronomic input traits (*i.e.*, traits that affect yield, quality, and ability to resist biotic and abiotic stressors—the vast majority of GE crops on the market). D. Zeljenková et al., "Ninety-day oral toxicity studies on two genetically modified maize MON810 varieties in Wistar Han RCC rats (EU 7th Framework Programme project GRACE)," 88 ARCHIVES OF TOXICOLOGY 2289 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4247492/pdf/204_2014_Article_1374.pdf (total of 17 partners from 13 countries involved) (Exhibit USA-140); P. Steinberg et al., "Lack of adverse effects in subchronic and chronic toxicity/ carcinogenicity studies on the glyphosate-resistant genetically modified maize NK603 in Wistar Han RCC rats," 93 ARCHIVES OF TOXICOLOGY 1095 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7261740/pdf/204_2019_Article_2400.pdf ("In conclusion, in the European GRACE and G-TwYST projects a series of animal feeding trials were performed (Zeljenková et al. 2014, 2016; this study). This series of studies neither delivered a scientific basis for the 90-day animal feeding trial demanded by the European Commission to be performed for each new GM plant variety nor did it indicate that untargeted, extended feeding studies with rats fed GM plant material are of value for a final confirmation of safety. Thus, an added value of animal studies relative to the available nonanimal studies for the risk assessment of GM plants (EFSA Scientific Committee et al. 2017) was not substantiated.") (Exhibit USA-141); X. Coumoul et al., "The GMO901 Project: Absence of Evidence for Biologically Meaningful Effects of Genetically Modified Maize-based Diets on Wistar Rats After 6-Months Feeding Comparative Trial," 168 TOXICOLOGICAL SCIENCES 315 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6432862/pdf/kfy298.pdf (Exhibit USA-142); *see also* European Food Safety Authority, "Safety and Nutritional Assessment of GM Plants and Derived Food and Feed: The Role of Animal Feeding Trials," 46 FOOD & CHEMICAL TOXICOLOGY S2 (2008), https://www.sciencedirect.com/science/article/abs/pii/S0278691508000884 ("In the situation where molecular, compositional, phenotypic, agronomic and other analyses have demonstrated equivalence between the GM plant derived food and feed and their near isogenic counterpart, except for the inserted trait(s), and do not indicate the occurrence of unintended effects, experiences with GM plants modified for agronomic input

| PARAGRAPH | EXHBIT | SOURCE TITLE | ANALYSIS |
|---|---|---|---|
| | | *hepatorenal toxicity"*. Arch Environ Contam Toxicol. | Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* ("Codex Guidelines").[3] Mexico has effectively taken the least valuable study in the food safety assessment and re-evaluated it. The article does nothing to refute other data and information used in the process that are more routinely relied upon for safety assessment. |
| 132 | MEX-127 | De Vendômois JS, Roullier F, Cellier D, Séralini GE. "*A comparison of the effects of three GM corn varieties on mammalian health"*. Int J Biol Sci. 2009. | This is also a re-analysis of a study conducted by a technology developer. Even if the authors' analysis were to be correct, this would only be one piece of data used in a safety assessment and typically at the exception to other more reliable studies. Moreover, Mexico's COFEPRIS already authorized the three GE corn events referenced here—MON810, MON863, and NK603—as have numerous other regulators around the world,[4] and Mexico has not offered any new analysis from COFEPRIS indicating a need to modify the original assessment, and the associated rationale. |
| 132 | MEX-128 | El-Shamei, Z. S., A.A. Gab-Alla, A. A. Shatta, E. A. Moussa & A. M. Rayan. (2012). "*Histopathological Changes in Some Organs of Male Rats Fed on Genetically Modified Corn (Ajeeb YG*)". Journal of American Science. | This is only one part of a safety assessment and even the article acknowledges that point. This is a study done as part of a PhD thesis in Egypt, which approved this variety (MON810) for cultivation (and which Mexico has approved for consumption). |

traits have demonstrated that the performance of 90-day feeding trials with rodents or feeding trials with target animal species have provided little if anything to the overall safety assessment (except for added confirmation of safety).") (Exhibit USA-143).

[3] Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* ("Codex Guidelines"), sec. 3, paras. 11-12 (Exhibit USA-114).

[4] *See* COFEPRIS Safety Evaluation of MON863 (Sept. 29, 2003) (Exhibit USA-144); COFEPRIS Safety Evaluation of MON810 (Nov. 6, 2002) (Exhibit USA-145); COFEPRIS Safety Evaluation of NK603 (June 7, 2002) (Exhibit USA-146); Food and Agriculture Organization of the United Nations ("FAO") Genetically Modified ("GM") Foods Platform, MON810 (listing assessments and authorizations in Australia, Brazil, Canada, China, the EU, Indonesia, Kenya, Malaysia, Mexico, New Zealand, Paraguay, the Philippines, South Korea, Singapore, Thailand, Turkey, the United States, Uruguay, and Vietnam) (Exhibit USA-147); FAO GM Foods Platform, NK603 (listing assessments and authorizations in Australia, Brazil, Canada, Colombia, the EU, Indonesia, Iran, Japan, Malaysia, Mexico, New Zealand, Paraguay, the Philippines, South Korea, Russia, Singapore, Thailand, Turkey, the United States, and Uruguay) (Exhibit USA-148); FAO GM Foods Platform, MON863 (listing assessments and authorizations in Australia, Canada, China, Colombia, the EU, Japan, Malaysia, Mexico, New Zealand, South Korea, Russia, Singapore, Thailand, Turkey, and the United States) (Exhibit USA-149).

| PARAGRAPH | EXHBIT | SOURCE TITLE | ANALYSIS |
|---|---|---|---|
| 132 | MEX-129 | Oraby, Hanaa; Kandil, Mahrousa; Shaffie, Nermeen; and Ghaly, Inas (2015) *"Biological impact of feeding rats with a genetically modified-based diet*" Turkish Journal of Biology: Vol. 39: No. 2, Article 11. | The test article in this study is not defined but rather is just listed as corn and soy without specifying which corn varieties. The study vaguely refers to "a laboratory diet of mainly 60% yellow maize and 34% soybeans," so it is impossible to attribute the effect seen to either corn or soy let alone a specific corn variety (none of which are defined). |
| 132 | MEX-131/132 | M.A.A. Ibrahim, E.F. Okasha, "*Effect of genetically modified corn on the jejunal mucosa of adult male albino rat"*, Exp Toxicol Pathol.; Zdziarski, I.M., Carman, J.A. and Edwards, J.W. (2018) "*Histopathological Investigation of the Stomach of Rats Fed a 60% Genetically Modified Corn Diet"*, Food and Nutrition Sciences. | These are additional rat-feeding studies that are considered the least reliable information in assessing food safety of whole foods when compared to the internationally accepted approach that relies on a comparative assessment of the safety of the new food and its conventional counterpart. |
| 132 | MEX-133/134 | Sagstad A, Sanden M, Haugland O, Hansen AC, Olsvik PA, Hemre GI. "*Evaluation of stress- and immune-response biomarkers in Atlantic salmon, Salmo salar L., fed different levels of genetically modified maize (Bt maize), compared with its near-isogenic parental line and a commercial suprex maize"*. J Fish Dis. 2007; Gu J, Krogdahl Å, Sissener NH, Kortner TM, Gelencser E, Hemre GI, Bakke AM. "*Effects of oral Btmaize (MON810) exposure on growth and health parameters in normal and sensitised Atlantic* | It is unclear how a study conducted on salmon, a non-mammalian animal, is relevant to human health in this dispute, nor does Mexico explain the significance of this study to human health.[5] |

[5] Studies that are used to evaluate potential genotoxicity in humans are established assays using mammalian systems. Mammalian laboratory animals, such as rats, mice, and rabbits, are used given the closer biological similarities to humans. Assays using non-mammalian species are not established to inform genotoxic risk in humans.

| PARAGRAPH | EXHBIT | SOURCE TITLE | ANALYSIS |
|---|---|---|---|
| | | *salmon, Salmo salar" L*. Br J Nutr. 2013. | |
| 132 | MEX-135 | Mesnage- Robin, Z-Sarah, Tenfen-Agapito, VilperteV-inicius, Renney-George, Ward- Malcolm, Séralini-Gilles Eric, O-Nodari Rubens and N-Antoniou, Michael (2016). "*An integrated multiomics analysis of the NK603 Roundup-tolerant GM maize reveals metabolism disturbances caused by the transformation process*". Nature. | This study looked at the metabolome of NK603 corn and reported: "The most pronounced metabolome differences between NK603 and its isogenic counterpart consisted of an increase in polyamines including N-acetyl-cadaverine (2.9-fold), N-acetylputrescine (1.8-fold), putrescine (2.7-fold) and cadaverine (28-fold), which depending on context can be either protective or a cause of toxicity." (p. 1). The paper also states, "Overall, whether the increased levels of cadaverine and putrescine found in the NK603 maize samples can account for the signs of potential negative health effects upon its consumption by rats, as implied by the blood/urine biochemical analysis, needs to be further analyzed in experiments using more quantitative methods." (p. 10). The author's conclusion that NK603 and its isogenic control are not substantially equivalent does not seem to be based on any objective standard as the analysis of N-acetyl-cadaverine, N-acetylputrescine, putrescine, or cadaverine is not recommended by the Organisation for Economic Co-operation and Development ("OECD") Consensus Document on the compositional analysis of corn, which provides guidance on what analytes should be measured when evaluating the food and feed safety of GE corn.[6] Of the thousands of chemicals present in corn only a few are likely to be meaningful in terms of food safety if their levels were to be changed.[7]<br><br>Finally, as with other studies of this type, changes in molecular markers such as of oxidative stress, do not necessarily indicate that plant health is negatively affected.[8] |

[6] OECD, "Consensus Document on Compositional Considerations for New Varieties of Maize (Zea Mays): Key Food and Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites," Table 14 (Aug. 20, 2002), https://one.oecd.org/document/env/jm/mono(2002)25/en/pdf (Exhibit USA-150).

[7] Moreover, cadavarine is often associated with rotting tissue, meaning that the increase in cadavarine could be a sign that the sample was not in good condition. This is yet another example of Mexico alleging issues but not actually taking subsequent steps to confirm that these are, in fact, food safety issues.

[8] J.E. Chambers et al., "Biomarkers as Predictors in Health and Ecological Risk Assessment," 8 HUMAN AND ECOLOGICAL RISK ASSESSMENT: AN INTERNATIONAL JOURNAL 165 (June 2010) ("[T]he degree of inhibition can be readily influenced by endogenous (*e.g.*, age) and exogenous (*e.g.*, chemical exposures) factors, and [] the degree of inhibition is not readily correlated with toxicological effects. Caution is urged, therefore, in an attempt to utilize biomarkers in the risk assessment process until more complete documentation is available on the specificity, sensitivity, and time course of changes, and on the impact of multiple exposures or the time of exposures.") (Exhibit USA-151).

| PARAGRAPH | EXHBIT | SOURCE TITLE | ANALYSIS |
|---|---|---|---|
| 132 | MEX-136 | Walsh MC, Buzoianu SG, Gardiner GE, Rea MC, Ross RP, Cassidy JP, Lawlor PG. "*Effects of shortterm feeding of Bt MON810 maize on growth performance, organ morphology and function in pigs".* Br J Nutr. 2012. | "Higher feed intake" is not necessarily an adverse health outcome. Feed conversion rates are a measure of growth performance and not necessarily safety. |
| 132 | MEX-137 | Carman, J. A., et al. (2013). "*A long-term toxicology study on pigs fed a combined genetically modified (GM) soy and GM maize diet. Journal of Organic Systems."* | This study used a mixture of GE corn varieties and GE soy, and thus attributing any effects seen would be very challenging. One would not expect a credible food safety study to be performed this way with a diet that is so ill-defined with multiple variables. |
| 132 | MEX-138 | Glöckner, G. & G-É. Séralini. (2016). "*Pathology reports on the first cows fed with Bt176 maize"* (1997–2002). Scholarly J. Agric. Sci. | This anecdotal paper expressly states that "it was not designed as a scientific experiment." It reports observations that can be useful in forming hypotheses, which can be further tested scientifically, but as observations do not, in and of themselves, demonstrate a safety concern.[9] |
| 133 | MEX-139 | Mesnage R, Clair E, Gress S, Then C, Székács A, Séralini GE. "*Cytotoxicity on human cells of Cry1Ab and Cry1Ac Bt insecticidal toxins alone or with a glyphosate-based herbicide".* J Appl Toxicol. | This is an in vitro study in which the Cry1Ab protein was presented to cells in culture. This has limited applicability to human health because one would expect the Cry1Ab protein to be digested and broken down to its component amino acids well before it reached the kidney. This is not the type of study that would be useful to a safety assessment of a *Bt* corn variety. This study admits: "The exposure during consumption can appear low enough to avoid side effects, and whether this occurs in vivo remains to be checked." (p. 3). Cells in real life are never exposed at these concentration levels. |
| 134 | MEX-140 | Monica Andreassen, Elena Rocca, Thomas Bøhn, Odd-Gunnar | This study states the opposite of what Mexico asserts.[10] In any event, the fact that pollen, plant debris, or even Cry1Ab protein may be an inhalant allergen |

[9] Furthermore, contrary to what Mexico states, the referenced paper was not why Bt176 was withdrawn; the reason was the presence of an ampicillin-resistance selection marker, and ampicillin is one of the antibiotic resistance issues the EU wanted to manage. However, studies found no horizontal gene transfer to infectious bacteria from Bt176 corn. *See, e.g.*, E. Badosa et al., "Lack of detection of ampicillin resistance gene transfer from Bt176 transgenic corn to culturable bacteria under field conditions," 48 FEMS MICROBIOLOGY ECOLOGY 169 (May 2004), https://onlinelUSAibrary.wiley.com/doi/epdf/10.1016/j.femsec.2004.01.005 (Exhibit USA-152).

[10] Mexico's Initial Submission alleges "[i]mmunogenicity and allergenicity from inhalation of pollen and plant debris from GM Bt corn (MON810), as well as exposure to purified Cry1Ab proteins." Mexico's Initial Submission, para. 134 (citing MEX-140). MEX-140 states: "No anti-Cry1Ab antibodies were detected following exposure to the plant materials." (p. 521).

| PARAGRAPH | EXHBIT | SOURCE TITLE | ANALYSIS |
|---|---|---|---|
| | | Wikmark, Johnnie van den Berg, Martinus Løvik, Terje Traavik & Unni Cecilie Nygaard (2015) "*Humoral and cellular immune responses in mice after airway administration of Bacillus thuringiensis Cry1Ab and MON810 cry1Ab-transgenic maize"*, Food and Agricultural Immunology. | does not mean that it is unsafe when present in food. Mexico's measures focus on food, not aeroallergens. This is not the type of test typically considered in the internationally accepted Codex Guidelines. |
| 135 | MEX-141 | Shen, C., Yin, XC., Jiao, BY. et al. "*Evaluation of adverse effects/events of genetically modified food consumption: a systematic review of animal and human studies"*. Environ Sci Eur 34, 8 (2022). | This is a literature review of published studies. The only human data reported was from one crossover study that is not relevant to corn because the test article was camelina. |
| 137 | MEX-142 | Futuyma, D. J. (2013). "*Evolution"*. Third edition. Sunderland, Massachusetts U.S.A, Sinauer Associates, Inc. Publishers. | Mexico states: "There are mechanisms that can modify the evolutionary structure of individuals within a population, such as gene flow, which is the transfer of genes from one population to another." The United States does not dispute this statement. This is true and it is a natural phenomenon that occurs absent of genetic engineering. |
| 138 | MEX-143/144 | Herrero, M., E. Ibañez, P. J. Martín-Álvarez and A. Cifuentes (2007). "A*nalysis of Chiral Amino Acids in Conventional and Transgenic Maize*" Anal. Chem; Levandi, T., C. Leon, M. Kaljurand, V. García-Cañas and A. Cifuentes (2008). "*Capillary Electrophoresis Time-of-Flight Mass Spectrometry for Comparative Metabolomics of Transgenic versus Conventional Maize*". Anal. Chem. | These phenomena—disparities in the content and chirality of amino acids and differences in the production of metabolites—typically are not themselves safety concerns. |
| 138 | MEX-145 | Agapito-Tenfen, S.Z., M.P. Guerra, R.O. Nodari & O. Wikmark. (2020*). "Untargeted Proteomics-Based Approach to Investigate Unintended Changes in Genetically* | This paper identifies a potential allergenic protein in its sample set, and does not determine that the protein is an allergenic protein, contrary to what Mexico states in paragraph 138 of its Initial Submission. |

| PARAGRAPH | EXHBIT | SOURCE TITLE | ANALYSIS |
|---|---|---|---|
| | | *Modified Maize Used for Food and Feed Purposes"*. Preprints. | |
| 138 | MEX-146 | Benevenuto, R. F., H. J. Venter, C. B. Zanatta, R. O. Nodari & S. Z. Agapito-Tenfen. (2022). "*Alterations in genetically modified crops assessed by omics studies: Systematic review and meta-analysis"*. Trends in Food Science & Technology. | This article does not present any adverse effects on plant health or food safety but rather just proposes that omics could be incorporated into a risk assessment process. |
| 139 | MEX-147 | Giraldo, P. A., Shinozuka, H., Spangenberg, G. C., Smith, K. F., & Cogan, N. O. I. (2021). "*Rapid and Detailed Characterization of Transgene Insertion Sites in Genetically Modified Plants via Nanopore Sequencing"*. Frontiers in plant science. | Mexico's claim that "any modification of the genetic material of any species, have an enormous and possibly irreversible effect on the way it evolves" also applies to corn bred through traditional breeding, including native Mexican varieties. This phenomenon is not unique to GE corn. |
| 139 | MEX-148 | Bushey DF, Bannon GA, Delaney BF, Graser G, Hefford M, Jiang X, Lee TC, Madduri KM, Pariza M, Privalle LS, Ranjan R, Saab-Rincon G, Schafer BW, Thelen JJ, Zhang JX, Harper MS. "*Characteristics and safety assessment of intractable proteins in genetically modified crops"*. Regul Toxicol Pharmacol, 2014. | This paper shows the exact opposite of what Mexico is arguing. Mexico alleges that "the expression of new proteins can trigger allergic reactions whose effects are not estimated in comparative analysis." The paper shows the diligence that scientists are taking to consider how to assess the potential allergenicity of proteins that may have physical characteristics that make them hard to assess by the typical processes. There is an entire annex to the Codex Guidelines that explains how to perform an allergenicity assessment.[11] |
| 144 | MEX-155 | Oraby HA, Kandil MH, Hassan AAM, Al-Sharawi HA. 2014. "*Addressing the issue of horizontal gene transfer from a diet containing genetically modified components into rats tissues"*. Afr J Biotechnol. | This is a poorly performed study that lacked controls investigating whether components in common between the test and control diet would each appear in these tissues. The researchers sampled tissues of liver and brain, but did not show that the DNA was in the cells (as opposed to blood or fluid) such that when new cells were produced the new cells also had the DNA. Presence of antibiotic resistance genes in blood and fluid is not a hazard. What could possibly start to be a hazard were if it were incorporated into certain cells of the body, but the study did not show that. Further, this article vaguely refers to "laboratory chow |

[11] *See* Codex Guidelines, Annex 1 ("Assessment of Possible Allergenicity") (Exhibit USA-153).

| PARAGRAPH | EXHBIT | SOURCE TITLE | ANALYSIS |
|---|---|---|---|
| | | | containing mainly 60% of yellow maize and 34% of soybeans," so it is impossible to attribute the effect seen to either corn or soy let alone a specific corn variety. |
| 144 | MEX-156 | Oraby, H.AS., Aboul-Maaty, N.AF., Al-Sharawi, H.A. et al. 2022. "*Horizontal transfer of antibiotic resistance genes into microflora and blood cells in rats fed on GM-diet"*. Bull Natl Res Cent. | This study states that "[n]one of these animal diets were labeled as genetically modified" (p. 2) but purports to show that the diets contain genetic elements often used in genetic engineering. The article states: "Animal feed samples were obtained from different animal feed suppliers in Cairo." As a result, it is not clear (i) what the test article was; (ii) whether it was, in fact, genetically engineered or how much of it was genetically engineered; (iii) where the researchers actually purchased the food; or (iv) how someone could repeat the study. A scientific study should be well-documented so that others can perform the same study and confirm the results. Given that the test material was not generally well characterized, it is very difficult to interpret this study. The study also should have had a control group that received diet without the genetic elements to show that what the authors were measuring was not an artifact of something other than the diet. The paper also does not say how the researchers chose which bacterial colonies to study after culturing 24-48 hours, or what kinds of bacteria were present. For example, it is possible that some of the bacteria could have naturally contained the antibiotic resistance markers, as some bacteria naturally contain the genes that the researchers looked for. It would have been important to rule out that the bacteria the researchers found did not naturally have the genes they were intending to detect. |
| 145 | MEX-157 | ISAAA. (s/f). "*GM Events with Antibiotic resistance. International Service for the Acquisition of Agribiotech Applications.* | As Mexico notes: "At the international level, there is a record of 161 approved GM events with antibiotic resistance, several of which are edible plants, including corn with 34 events." Rather than supporting Mexico's position, these data just reinforce how inconsistent Mexico's views are compared to other regulators around the world. By Mexico's own language, regulators chose to approve events with antibiotic resistance markers more than 34 times based on scientific evidence of safety. The Codex Guidelines address how to assess the safety of antibiotic resistance markers.[12]<br><br>Moreover, these antibiotic resistance markers are just "selection markers," which are tools developers use in the process of developing the transgenic crop, and not intended to confer resistance to antibiotics in the field. |

[12] Codex Guidelines, sec. 5, paras. 55-58 (Exhibit USA-114).

| PARAGRAPH | EXHBIT | SOURCE TITLE | ANALYSIS |
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| | | | |
| 146 | No citation | N/A | Mexico claims, citing nothing, that "[s]ince 2013, robust scientific evidence (over 1000 human samples from four independent studies) have shown that DNA fragments large enough to carry genes from food can avoid degradation and enter the human circulatory system." This statement appears to refer to MEX-158 (below). This study does not mention that the DNA obtained from food was stably integrated into the human DNA, let alone expressing any proteins. The presence of food-origin DNA in the blood stream is not harmful, and MEX-158 does not distinguish transgene DNA from any other DNA that was present in the plant. |
| 146 | MEX-158 | Spisák S, Solymosi N, Ittzés P, Bodor A, Kondor D, Vattay G, Barták BK, Sipos F, Galamb O, Tulassay Z, Szállási Z, Rasmussen S, Sicheritz-Ponten T, Brunak S, Molnár B, Csabai I. *"Complete genes may pass from food to human blood"*. PLoS One. 2013. | Mexico claims that "[S]tudies in animals (trout, goats, pigs and mice) fed GMO diets support this idea [that DNA fragments from food can enter the human circulatory system], which means that these fragments have been found in the digestive tract and leukocytes." The studies cited in this article do not appear to address consumption of GE corn (and nonmammalian trout are irrelevant as it relates to adverse effects in humans in this case). This article also did not report or evaluate stable integration into the DNA of the organism consuming it. |
| 147-148 | MEX-044 | Chávez, C., Virgen-Ortiz, J. J., Serrano-Rubio, L. E., Martínez-Téllez, M. A., & Astier, M., "*Comparison of nutritional properties and bioactive compounds between industrial and artisan fresh tortillas from corn landraces*", 2020, Current Research in Food Science. | Mexico claims that "GM corn has reduced levels of protein, fiber and antioxidants compared to native corn varieties." The cited article does not even address GE corn. The article discusses blue tortillas, white tortillas, and industry-made tortillas. The "BT" referred to in this article refers to blue tortillas.<br><br>Similarly, Mexico claims: "GM corn has demonstrated marked disparities in its levels of macronutrients, micronutrients and essential minerals compared to native corn," citing this article. Again, this article does not investigate GE corn, but rather it focuses on nutritional value of tortillas made from blue corn, white corn, or industrial corn. The article provides no evidence to indicate where the corn is sourced from or whether any of the corn is GE. |
| 148 | MEX-049 | De la Parra, C., Serna Saldivar, S. O., & Liu, R. H. "*Effect of processing on the phytochemical profiles and antioxidant activity of corn for production of masa, tortillas, and tortilla chips*, 2007, | Mexico alleges that "[s]ince [GE corn] come[s] mostly from commercial hybrid lines of corn, they have a lower amount of phenolic compounds and anthocyanins and, therefore, a lower antioxidant capacity," citing this article. This article is about the processing of corn in general and is not specific to GE corn. Whether GE or not, most commercialized corn varieties are hybrid varieties. |

| PARAGRAPH | EXHBIT | SOURCE TITLE | ANALYSIS |
|---|---|---|---|
| | | Journal of Agricultural and Food Chemistry. | |
| 149 | MEX-068 | Steven A. Abrams, Jaclyn Lewis Albin, Philip J. Landrigan. Committee on nutrition, council on environmental health and climate change. (2023). "*Use of Genetically Modified Organism (GMO)-Containing Food Products in Children. Pediatrics."* | Mexico cites this article as support for the contention that GE foods are used to produce large quantities of nutritionally-deficient "ultra-processed foods." This article suffers from numerous deficiencies. Although the article claims "widespread use of GMO ingredients in food, including nearly all ultra-processed foods in the United States," there is not a clear equivalency to the use of GE-derived ingredients and "ultra-processed" foods, and the article does not cite any scientific studies to support such equivalency. In addition, this paper places undue emphasis on the International Agency for Research on Cancer ("IARC") classification of glyphosate as "probably carcinogenic to humans" in 2015 (*see also* analysis of this IARC classification in MEX-301, below). The article does not acknowledge that IARC did not assess the risks of glyphosate residues on or in food but simply identified the hazards potentially associated with glyphosate in general, without consideration of exposure levels. Nor does the article acknowledge that subsequent to the IARC classification, the joint Food & Agriculture Organization of the United Nations ("FAO")/World Health Organization ("WHO") Meeting on Pesticide Residues ("JMPR") considered the body of evidence for cancer outcomes for glyphosate, including the studies reviewed by the IARC and additional relevant studies, and still concluded that glyphosate "is unlikely to pose a carcinogenic risk to humans via exposure from the diet."[13] This article also does not acknowledge the conclusions of multiple global regulatory authorities and experts that glyphosate is not likely to be carcinogenic to humans (*see* analysis of MEX-301, below).<br><br>Finally, the article implies that consumption of GE products is inherently associated with increased pesticide exposures and that exposure to pesticide residues inherently means there is increased risk. These implications relate to a misunderstanding, or lack of awareness, of pesticide tolerances and the rigorous assessments that support those determinations. The article also ignores that pesticides may be used on both GE and non-GE crops (*see* Annex II, concerning agrochemical usage and GE crops). The risk of an exposure depends on the toxicity of the compound and the type and amount of exposure. It is not accurate |

[13] Joint FAO/WHO Meeting on Pesticide Residues ("JMPR"), "Pesticide Residues in Food – 2016: Toxicological Evaluations," at 257 (May 2016) (Exhibit USA-154). When glyphosate was last evaluated by JMPR in 2019, the Meeting concluded that acute and long-term dietary exposures to residues of glyphosate are unlikely to present a public health concern for the uses considered by JMPR. Extra Joint FAO/WHO Meeting on Pesticide Residues, "2019 Report – Pesticide Residues in Food," at 81 (2019) (Exhibit USA-155).

| PARAGRAPH | EXHBIT | SOURCE TITLE | ANALYSIS |
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| | | | to imply that any exposure to glyphosate residues in one's diet necessarily results in an increase in risk of adverse health effects, as the United States further explains in Section IV.A of its Rebuttal. |
| 150 | MEX-160 | Matos, R.A., Adams, M., Sabaté J. (2021). "*Review: The consumption of ultra-processed foods and noncommunicable diseases in Latin America"*. Frontiers in Nutrition. | Mexico asserts that "[t]he impact of these ultra-processed foods on the Mexican diet is alarming." Genetic engineering has nothing to do with ultra-processed foods, to the extent the latter is even a health issue. Foods well beyond corn can be used as ingredients in ultra-processed products, such as wheat, canola, cottonseed, and even sugar, and is not something unique or specific to genetic engineering. This article does not discuss information about corn, let alone GE corn. |
| 181 | MEX-217 | Krimsky, S. (2015). "*An Illusory Consensus behind GMO Health Assessment."* Science, Technology & Human Values. | Mexico, in claiming that "[t]he safety of GMOs is completely illusory," is simply reiterating the title of the paper, which is emotive. The author provides a review of the literature, much of which has shown no negative health impacts of GE foods and feed, and uses a methodology that is ill-defined but appears to be the result of keyword searches. |
| 181 | MEX-218 | Hilbeck, A., Binimelis, R., Defarge, N. et al. "*No scientific consensus on GMO safety"*. Environ Sci Eur 27, 4 (2015). | This is a statement purportedly signed by 300 researchers (who are not listed in this paper); it is not a research article. The main point of this paper is that a blanket statement of food and environmental safety for all GMOs cannot be made and thus the Cartagena Protocol on Biosafety and Codex advocate for reviews on a case-by-case basis. If Mexico agrees with this statement, then Mexico should conduct a case-by-case risk assessment, as the United States argued in its Initial Submission and this Rebuttal. The statement relies on multiple Séralini studies (*see* Section II.A of U.S. Rebuttal) and also cites blog posts, some of which no longer exist, as well as Wikipedia. |
| 185 | MEX-225 | Séralini GE, Clair E, Mesnage R, Gress S, Defarge N, Malatesta M, Hennequin D, de Vendômois JS. Republished study: "*long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified corn"*. Environ Sci Eur. 2014. | This is a republication of Séralini's retracted 2012 study (*see* Section II.A of U.S. Rebuttal). The study concludes: "Our findings imply that long-term (2 year) feeding trials need to be conducted to thoroughly evaluate the safety of GM foods and pesticides in their full commercial formulations." The EU has thoroughly evaluated the need for such feeding trials and has uniformly concluded across three comprehensive studies that they are not routinely warranted.[14] The value of long-term studies has also been refuted by Codex since 2003.[15] |

[14] *See supra* Analysis of MEX-128.

[15] Codex Guidelines, sec. 3, para. 11-12 (reflecting consensus that animal studies, including long-term animal studies, are not widely accepted to assess the safety of whole foods and are extremely difficult to interpret) (Exhibit USA-114). As of March 2024, the United States has completed more than 200 evaluations of food from genetically engineered or genome edited plants and has not yet seen a need to request such a study.

| PARAGRAPH | EXHBIT | SOURCE TITLE | ANALYSIS |
|---|---|---|---|
| | | | Moreover, the journal provides a disclaimer that it is republishing the study for transparency but disclaims its contents: "ESEU aims to enable rational discussions dealing with the article from G.-E. Séralini et al. (Food Chem. Toxicol. 2012, 50:4221–4231) by re-publishing it. By doing so, any kind of appraisal of the paper's content should not be connoted. The only aim is to enable scientific transparency and, based on this, a discussion which does not hide but aims to focus methodological controversies." (p. 2). |
| 193 | MEX-085 (citing MEX-125) | CONAHCYT, "*Scientific Record on Glyphosate and GM Crops*", 2020 (in turn citing González-Ortega, E., Piñeyro-Nelson, A., Gómez-Hernández, E., Monterrubio-Vázquez, E., Arleo, M., Dávila-Velderrain, J., Martínez-Debat C. y Álvarez-Buylla E. R., "*Pervasive presence of transgenes and glyphosate in corn-derived food in Mexico*", 2017). | MEX-125 is not a risk assessment of glyphosate (or of dietary exposure to glyphosate) but rather focuses on identifying transgenes and glyphosate in Mexico. This paper is a snapshot in time at a specific location of a limited number of processed maize-based food samples (as opposed to raw agricultural commodity samples) pulled from a marketplace and tested for the presence of transgenes and glyphosate residues. Due to the methods used, the presence of glyphosate cannot be conclusively connected to the application of glyphosate to glyphosate-tolerant corn. Glyphosate is used extensively, and there are many potential sources along the value chain. The glyphosate residues detected are well below the trade standard maximum residue limits ("MRLs"). The majority of the transgene-containing samples contained no detectable glyphosate residues at all, according to the analytical methods in the study. Risk is a function of exposure and toxicity, and the presence of residues alone does not equate to risks. |

**ANNEX II - ASSESSMENT OF STATEMENTS IN MEXICO'S INITIAL SUBMISSION CONCERNING AGROCHEMICAL USAGE AND GE CROPS[16]**

| PARAGRAPH | ALLEGATION | ANALYSIS |
|---|---|---|
| 92 | "A systemic herbicide (and the contaminants or toxins into which it can be broken down within the plant) cannot be 'washed out' because it accumulates within the plant itself." | This is not accurate. Glyphosate is rapidly metabolized in plants and does not persist in the organism.[17] |
| 93 | "GMO do not reduce the amount of agrochemicals." | This is a highly nuanced space, and context is key. Studies have actually found that herbicide use has risen more quickly with non-GE crops than GE crops.[18] However, usage alone is not a good measure, because the toxicity of each pesticide is not directly related to the amount (weight) applied and there is no consideration of how the active ingredients disperse into the environment.[19] When the environmental impact quotients ("EIQ") are calculated—a measure incorporating the amounts applied and their relative toxicity to particular environmental indicators such as fish or pollinators—there is a net decrease in the EIQ with GE crops.[20] The chronic toxicity for herbicides used in maize remained unchanged between 1990 and 2015 (even while acre treatments increased), and acute toxicity for herbicides used in maize fell 88% over this same time period, largely because glyphosate replaced older and more toxic herbicides previously used more widely.[21] |

[16] To the extent the United States has not commented on a particular statement by Mexico in its Initial Submission, such an omission does not imply an endorsement of the statement's credibility or accuracy.

[17] *See, e.g.*, S. Duke, "Enhanced Metabolic Degradation: The Last Evolved Glyphosate Resistance Mechanism of Weeds?," 181 PLANT PHYSIOLOGY 1401 (2019) (Exhibit USA-156).

[18] *See, e.g.*, A. Kniss, "Long-term Trends in the Intensity and Relative Toxicity of Herbicide Use," NATURE COMMUNICATIONS (Apr. 2017) (Exhibit USA-157).

[19] *See* 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, 264 (2022), https://www.tandfonline.com/doi/epdf/10.1080/21645698.2022.2118497?needAccess=true&role=button (Exhibit USA-46).

[20] *Id.* at 277 (finding 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) (Exhibit USA-46).

[21] A. Kniss, "Long-term Trends in the Intensity and Relative Toxicity of Herbicide Use," NATURE COMMUNICATIONS, at 3 (Apr. 2017) (Exhibit USA-157).

| PARAGRAPH | ALLEGATION | ANALYSIS |
|---|---|---|
| 94 | "Bt technology has also failed to reduce the use of insecticides." | Mexico cites nothing to support this statement, and it is simply not true.[22] |
| 94 | "[T]he insecticidal toxins produced by GM plants have led to the development of resistance in pest insects, which would indicate that Bt technology is environmentally and agronomically unsustainable." | The scientific community has always known that *Bt* resistance was going to occur. Resistance to *Bt* powders in diamondback moth was first reported in 1990, and resistance management has always been part of GE corn and cotton production.[23] |
| 158 | "[G]lyphosate is a highly dangerous pesticide and this is irrefutable." | Mexico cites the U.S. Environmental Protection Agency's ("EPA") "Draft National Level Listed Species Biological Evaluation for Glyphosate," which does not lead to the conclusion that Mexico alleges. EPA submitted a "Final National Level Listed Species Biological Evaluation for Glyphosate" to the U.S. Fish and Wildlife Service and National Marine Fisheries Service to initiate formal consultation under section 7 of the Endangered Species Act. This document is not relevant for a human health risk assessment and is limited in scope to potential impacts on endangered and threatened animal and plant species and their critical habitats from the application of glyphosate and subsequent exposure to non-target wildlife and plants within the United States. The purpose of this document was not to determine if glyphosate is "dangerous" for purposes of a human health risk assessment.[24] |
| 161 | "[T]he main function of GM corn is to tolerate greater amounts of herbicides, specifically glyphosate. This means that direct consumption of GM corn results in | It is incorrect to assume that plants that are tolerant to glyphosate automatically will have higher residues of glyphosate in the edible plant parts. The amount of pesticide applied, and the timing of application both impact residue levels. An example of this can be seen in the glyphosate residue data that the JMPR |

[22] *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 (Bt) maize used 11.2 percent (0.013 kilogram per hectare) less insecticide than nonadopters) (Exhibit USA-47).

[23] *See, e.g.*, B. Tabashnik, "Evolution of Resistance to *Bacillus Thuringiensis*," 39 ANNUAL REVIEW OF ENTOMOLOGY 47 (1994) (Exhibit USA-158).

[24] For additional context, EPA's Biological Evaluations are by design very conservative in nature and rely on the worst-case exposure scenarios (maximum application rates, shortest application intervals, maximum number of applications per year). The objective of a Biological Evaluation is to make the determination as to whether use of glyphosate is Not Likely to Adversely Affect or Likely to Adversely Affect each of the 1,795 threatened and endangered species in the United States. EPA's threshold for this determination is effects to a single individual of a given population of threatened or endangered species. Separate analyses are then carried out to determine if there are likely to be population-level effects. The exposure assumptions are very high, because the evaluation uses extremely conservative model inputs, and the bar for effects to threatened and endangered species is extremely low. This document does not have anything to do with glyphosate exposure from human dietary consumption (or any other form of human exposure), let alone human health risk from consuming GE corn.

| PARAGRAPH | ALLEGATION | ANALYSIS |
|---|---|---|
| | consuming a product that has been exposed to a greater amount of an herbicide[.]" | reviewed in 2005 (concerning conventional and glyphosate-tolerant maize) and 2011 (glyphosate-tolerant maize only). In 2005, the recommended MRL of 5.0 ppm was based on the conventional maize data. The 2011 meeting reconfirmed the previous MRL recommendation of 5.0 ppm because the dataset of conventional maize actually gave rise to a higher maximum residue level.[25] Residue levels are primarily a function of how glyphosate is used and not whether the crop is glyphosate-tolerant. From a dietary exposure and risk perspective, what matters is the potential residue level at the consumption point, not how much was applied in the field, and both GE and conventional corn can be treated with glyphosate. |
| 182 | "GBHs of commercial brands such as *Roundup* contain toxic agents such as petroleum derivatives and heavy metals." | The cited studies (MEX-219 & MEX-220) do not demonstrate actual risk upon consumption of the food products at biologically relevant levels. |
| 191 | "[A]pplication of glyphosate causes native corn to become even more exposed to insect pests." | The cited study (MEX-234) merely postulated this and did not present data. |

[25] JMPR, "Pesticide Residues in Food 2005," at 129-130, 144 (2005) (Exhibit USA-159); JMPR, "Pesticide Residues in Food 2011," at 155, 159 (2011) (Exhibit USA-160).

**ANNEX III - ASSESSMENT OF EXHIBITS IN MEXICO'S INITIAL SUBMISSION ALLEGING GLYPHOSATE EXPOSURE[26]**

| PARAGRAPH | EXHIBIT | SOURCE TITLE | ANALYSIS |
|---|---|---|---|
| 165 | MEX-183/184 | Krüger. M. et. al. (2014). "*Detection of Glyphosate Residues in Animals and Humans".* Environ Anal Toxicol 2014/ Krüger. M. et. al. (2013). "*Field Investigations of Glyphosate in Urine of Danish Dairy Cows"*. Environ Anal Toxicol 2013. | The presence of glyphosate in excreta does not mean there is an adverse health effect; elimination is expected.[27] To the extent residues appear in animal tissue, Codex and the United States (as well as other countries) have set MRLs for residues of glyphosate in meat byproducts (including liver and kidney). Neither MEX-183 nor MEX-184 analyzed samples of food or feed for residues of glyphosate or provided information how much (or the types) of food/feed was consumed by the livestock. Additionally, there are other limitations to the utility of these studies including that not all of the data were shown and the data were presented graphically. MEX-183 provided limited information (a graph) about residues observed in several livestock tissue samples. The highest levels were in lung tissue and were well below the Mexican and U.S. tolerance levels for residues of glyphosate in meat byproducts (1 ng/g = 0.001 ppm) and therefore would not be considered a risk of concern. |
| 406 | MEX-301 | IARC, "*Monograph on Glyphosate*", 2015. | The IARC report is not a risk assessment. The IARC is a cancer agency within the WHO whose purpose is to "identif[y] and classif[y] hazards," *i.e.*, to assesses whether a chemical product is capable of producing harm and what harm it may produce.[28] The IARC's work constitutes "hazard identification"— |

[26] To the extent the United States has not commented on a particular exhibit cited by Mexico in its Initial Submission, such an omission does not imply an endorsement of the exhibit's credibility or accuracy. As noted in the U.S. Rebuttal Submission, Mexico cited a large volume of studies that have nothing to do with glyphosate exposure through dietary consumption, let alone through consumption of GE corn. *See, e.g.*, Sections V.D.1.c, V.D.2.a, V.D.2.b.1, V.D.2.c. Nevertheless, in the interest of reinforcing the lack of relevance of Mexico's cited support, the United States will address certain exhibits that Mexico cited in relation to its Article 9.6.8(a) arguments, concerning its "risk assessment." *See* Mexico's Initial Submission, Section VII.E.4.

[27] A common, but erroneous, conclusion from biomonitoring data is that low levels of a chemical in a biological sample (*e.g.*, urine, blood) will be harmful to humans; however, detection is not equivalent to risk. Biomonitoring data requires conversion to estimated external dose levels in order to evaluate whether potential risks may exist. For instance, urinary glyphosate levels have been reported by several organizations and research groups, including the U.S. Centers for Disease Control and Prevention. Detection is expected given how glyphosate enters, distributes, breaks down, and exits the body. When converted to external doses, the estimated doses associated with these urinary levels are orders of magnitude lower than the current dietary reference dose (*i.e.*, the maximum acceptable oral dose of a substance, below which no adverse health effects should result from a lifetime of exposure).

[28] *See* Pan American Health Organization ("PAHO"), "Questions and Answers on the Use Diazinon, Malathion and Glyphosate" (Sept. 2015), https://www.paho.org/en/documents/questions-and-answers-use-diazinon-malathion-and-glyphosate-2015 (Exhibit USA-161).

| PARAGRAPH | EXHIBIT | SOURCE TITLE | ANALYSIS |
|---|---|---|---|
| | | | the first step in a "risk assessment."[29] A "risk assessment" would go on to evaluate exposure and characterize the overall level of risk.[30] The FAO/WHO JMPR is responsible for these subsequent steps and assesses the risk of pesticide residues in and on food.[31] The IARC did not assess the exposure and risks associated with glyphosate residues in or on food; instead, it identified and characterized the hazards potentially associated with glyphosate exposure, without consideration of exposure levels. The IARC report simply found that, at some level of exposure, glyphosate probably had the potential to increase the risk of a particular type of cancer (non-Hodgkin's lymphoma) in humans. The release of the IARC report expressly indicated that the IARC findings were neither a risk assessment nor a modification of the technical instructions for glyphosate.[32] Subsequently, the JMPR (the FAO/WHO pesticide risk assessment body) considered the body of evidence for cancer outcomes for glyphosate, including the studies reviewed by the IARC and additional relevant studies, and concluded that glyphosate "is unlikely to pose a carcinogenic risk to humans via exposure from the diet."[33] International expert panels and regulatory authorities—including the U.S. EPA[34], Australian Pesticide and |

[29] *See id.* at 3 (Exhibit USA-161); *see also* Panel Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States*, WT/DS26/R/USA, para. 8.103 (adopted Feb. 13, 1998) (Exhibit USA-162).

[30] *Id.* (Exhibits USA-161 & USA-162).

[31] PAHO, "Questions and Answers on the Use Diazinon, Malathion and Glyphosate," at 1 (Sept. 2015), https://www.paho.org/en/documents/questions-and-answers-use-diazinon-malathion-and-glyphosate-2015 ("JMPR is an international scientific group of experts administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and WHO, tasked with evaluating the risk associated with pesticide residues in food and elsewhere. It is also known as the Joint FAO/WHO Meeting.") (Exhibit USA-161).

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

[33] JMPR, "Pesticide Residues in Food – 2016: Toxicological Evaluations," at 257 (May 2016) (Exhibit USA-154).

[34] U.S. Environmental Protection Agency ("EPA"), "Human Health Risk Assessment in Support of Registration Review" (Dec. 12, 2017) (Exhibit USA-164); EPA Office of Pesticide Programs, "Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential" (Dec. 12, 2017) (Exhibit USA-173). In the United States, existing pesticides must be re-evaluated periodically to ensure that they continue to meet the appropriate safety standard, a process known as registration review. In December 2017, as part of glyphosate's ongoing registration review, EPA conducted a comprehensive human health risk assessment of glyphosate that considered hazard and exposure data, including an in-depth review of all relevant animal carcinogenicity and genotoxicity studies for the active ingredient glyphosate, as well as epidemiological studies that investigated potential cancer outcomes from using pesticide products containing glyphosate. EPA's risk assessment process combines hazard, dose-response, and exposure assessments to describe the overall risk from glyphosate. EPA's independent evaluation of the available scientific data for glyphosate found no risks of concern to human health when used in accordance with the current label instructions; found no indication that children are more sensitive to glyphosate; concluded that glyphosate is "not likely to be carcinogenic" to humans; and concluded that glyphosate

| PARAGRAPH | EXHIBIT | SOURCE TITLE | ANALYSIS |
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| | | | Veterinary Medicines Authority[35], Canadian Pest Management Regulatory Agency[36], European Food Safety Authority[37], European Chemicals Agency[38], German Federal Institute for Risk Assessment[39], New Zealand Environmental Protection Authority[40], and the Food Safety Commission of Japan[41]—have all found the available data on glyphosate sufficiently robust for deciding that there is no basis for human hazard concern with respect to this herbicide. The IARC Monograph's conclusion is not consistent with any other international organization or regulatory authority that has evaluated the carcinogenic potential of glyphosate. |
| 406 | MEX-305 | Martin, E., "*Glyphosate Toxicological Anthology*", 2020. | This is simply an annotated bibliography based on keyword searches of several databases of scientific journals. This is not a risk assessment nor do any of the listed titles present an appropriate assessment of risk from consuming GE corn that may have glyphosate residues. |
| 407 | MEX-304 | ATSDR U.S. Department of Health and Human Services. "*Agency for* | Mexico incorrectly states that the ATSDR toxicological profile makes findings that are consistent with the IARC Monograph (*see* analysis of MEX-301 |

does not interact with the thyroid, estrogen, or androgen signaling pathways based on a weight-of-evidence review. EPA anticipates issuing its final registration review decision on glyphosate in 2026. As part of registration review, EPA intends to revisit and further explain its evaluation of the carcinogenic potential of glyphosate, but the underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic to humans, currently remain the same. *See* EPA, "Glyphosate" (Sept. 2023), https://www.epa.gov/ingredients-used-pesticide-products/glyphosate (Exhibit USA-174).

[35] Australian Pesticides & Veterinary Medicines Authority, "Final Regulatory Position: Consideration of the Evidence for a Formal Reconsideration of Glyphosate" (Mar. 2017), https://www.apvma.gov.au/sites/default/files/publication/26561-glyphosate-final-regulatory-position-report-final_0.pdf (Exhibit USA-175); *see also* Australian Pesticides & Veterinary Medicines Authority, "Glyphosate" (last updated Oct. 2023), https://www.apvma.gov.au/resources/chemicals-news/glyphosate ("Glyphosate has also been assessed by other government regulators and independent scientists around the world. These assessments consistently found that glyphosate has low toxicity for humans, animals, fish, insects (including bees) and other invertebrates.") (Exhibit USA-176).

[36] Canada Pest Management Regulatory Agency, "Glyphosate – Re-evaluation Decision" (Apr. 2017), https://publications.gc.ca/collections/collection_2017/sc-hc/H113-28/H113-28-2017-1-eng.pdf (Exhibit USA-177).

[37] European Food Safety Authority ("EFSA"), "EFSA Explains the Scientific Assessment of Glyphosate" (July 2023), https://www.efsa.europa.eu/sites/default/files/2023-07/glyphosate_factsheet.pdf (Exhibit USA-178).

[38] European Chemicals Agency, "EU Glyphosate Renewal - Risk Assessment Committee opinion" (May 30, 2023), https://www.glyphosate.eu/grg/whatsnew/eu-glyphosate-renewal-risk-assessment-committee-opinion/ (Exhibit USA-179).

[39] German Federal Institute for Risk Assessment, "WHO/FAO committee (JMPR) re-assesses glyphosate and confirms the BfR and EFSA conclusion that a carcinogenic risk is not to be expected" (May 2016), https://www.bfr.bund.de/cm/349/who-fao-committee-jmpr-re-assesses-glyphosate-and-confirms-the-bfr-and-efsa-conclusion-that-a-carcinogenic-risk-is-not-to-be-expected.pdf (Exhibit USA-180).

[40] New Zealand Environmental Protection Authority, "Review of the Evidence Relating to Glyphosate and Carcinogenicity" (Aug. 2016), https://www.epa.govt.nz/assets/Uploads/Documents/Everyday-Environment/Publications/EPA-glyphosate-review.pdf (Exhibit USA-181).

[41] Food Safety Commission of Japan, "Glyphosate – Summary" (Sept. 2016), https://www.jstage.jst.go.jp/article/foodsafetyfscj/4/3/4_2016014s/_pdf/-char/en ("Glyphosate had no neurotoxicity, carcinogenicity, reproductive toxicity, teratogenicity, and genotoxicity.") (Exhibit USA-182).

| PARAGRAPH | EXHIBIT | SOURCE TITLE | ANALYSIS |
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| | | *Toxic Substances and Disease Registry. Toxicological Profile for Glyphosate*", 2020. | above). Although the glyphosate ATSDR toxicological profile summarizes current studies and conclusions from other organizations and regulatory authorities related to carcinogenic potential, ATSDR did not conduct an independent cancer evaluation and merely referenced the IARC classification alongside summarizing other studies. Mexico similarly alleges that the ATSDR shows a "strong correlation between exposure" and certain adverse effects (Mexico's Initial Submission, para. 406) without any consideration of the doses where the effects were observed. |
| 408 | MEX-306 | Vandenberg, L.N., Colborn, T., Hayes, T.B., Heindel, J.J., Jacobs, Jr., D.R., Lee, D.H., Shioda, T., Soto, A.M., vom Saal, F.S., Welshons, W.V., Zoeller, R.T. y Peterson Myers, J. "*Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses*" 2012. | This study does not have anything to do with GE corn. Mexico claims: "Data and information from animal studies and human cell studies suggest that exposure to low doses of glyphosate effects hormone levels and reproductive systems, leading to endocrine disruption." The cited study does not describe glyphosate in depth, and only mentions it among others in Table 6 (where it is erroneously referred to as "glyphosphate"). It is unclear what methods or levels of exposure are being addressed, or the details of the alleged findings. |
| 408 | MEX-307 | Ingaramo, P., "*Are glyphosate and glyphosate-based herbicides endocrine disruptors that alter female fertility*?". | This study does not have anything to do with GE corn. This is a review article, with no new data presented. The overall conclusions of this article are unclear.[42] |
| 408 | MEX-308 | Davico, C. E, Pereira, A.G., Nezzi, L., Jaramillo, M.L., de Melo, M.S., Müller, Y.M.R., y Nazari, E.M., "*Reproductive toxicity of Roundup WG® herbicide: impairments in ovarian follicles of model organism Danio rerio*". | This study used a formulated product (Roundup WG® (RWG)), and dose concentrations appear to be based on the formulated product, as opposed to glyphosate. As such, potential effects cannot be attributed to glyphosate exposure. |
| 408 | MEX-431 | Masood, M.I, Mahrukh Naseem, S., Warda, A., Tapia-Laliena, M.A., ur Rehman, H., Nasim, M.J. and | The study examined isolated stem cells from animals not exposed to the compound. The cells were exposed in vitro in a petri dish. The test compound was the technical grade material, and not the formulated product. This is not a |

[42] In addition to the lack of relevance, this study discusses reproductive effects observed in a study by Almeida et al. (2017) where rodents were exposed to 500 mg/kg of a glyphosate-containing product, which is considered relatively high for mammalian toxicological studies and would not typically be considered relevant for a human health risk assessment. This study does not report effects at doses that would be considered "low levels," contrary to what Mexico asserts. *See* Mexico's Initial Submission, para. 408.

| PARAGRAPH | EXHIBIT | SOURCE TITLE | ANALYSIS |
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| | | Schäfer, K.H., "*Environment permissible concentrations of glyphosate in drinking water can influence the fate of neural stem cells from the subventricular zone of the postnatal mouse*". | risk assessment of dietary exposure to glyphosate, nor does this study have anything to do with GE corn. |
| 408 | MEX-310 | Kubsad, D., Nilsson, E.E., King, S.E., Sadler-Riggleman, I., Beck, D. and Skinner, M.K., "*Assessment of Glyphosate Induced Epigenetic Transgenerational Inheritance of Pathologies and Sperm Epimutations: Generational Toxicology*," in "*Scientific Reports."* | This study found no effects in the parental or first generation following intraperitoneal (gut) injections to gestating rats, but effects on the second and third generations in terms of ≥1 disease at one year of age—however, there was no clear pattern when looking at any one disease. This is not a risk assessment of dietary exposure to glyphosate through dietary consumption of GE corn. |
| 408 | MEX-311 | Wilson, VS, Bobseine, K, Lambright, CR, Gray, LE Jr., "*A novel cell line, MDA-kb2, that stably expresses an androgen- and glucocorticoid-responsive reporter for the detection of hormone receptor agonists and antagonists."* | Mexico falsely alleges that "[t]he endocrine involvement of exposure to low doses of glyphosate in humans was demonstrated by assays in MDA-kb2 cell lines that allow the detection of hormone receptor antagonists, and in placental JEG3 cell lines." The cited study (MEX-311) does not even mention glyphosate. This study also does not reference GE corn. |
| 408 | MEX-312/207/193 | Richard S., Moslemi S., Sipahutar H., Benachour N., Séralini G-E., "*Differential effects of glyphosate and roundup on human placental cells and aromatase*", 2005/Mesnage, R., Bernay, B., Séralini, G.E. (2013). "*Ethoxylated adjuvants of glyphosate-based herbicides are active principles of human cell toxicity"*. Toxicology/ Benachour, N. y Séralini, G.E. "*Glyphosate Formulations Induce Apoptosis and Necrosis in Human* | These studies expose isolated cells to technical grade glyphosate and formulated RoundUp. There is no discussion if the concentrations tested are likely to be relevant to circulating levels of glyphosate within an organism. Ingested or absorbed pesticides do not circulate within the organism at the concentration they are exposed to; rather, the concentration is usually significantly less. These studies are not a dietary risk assessment, nor do they have anything to do with consumption of GE corn.<br><br>In fact, none of the articles Mexico has cited has had a comparison of the concentrations causing effects on cells in a petri dish to what concentrations are circulating in the body following exposure. Without that information, one cannot say if the tested concentrations have any relevance to real-world exposures or not.[43] |

[43] These studies have several limitations that have been previously identified that would limit their ability to be used in a risk assessment context. *See* EPA, "Glyphosate - Systematic Review of Open Literature" (2017), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0067 (Exhibit USA-163). For

| PARAGRAPH | EXHIBIT | SOURCE TITLE | ANALYSIS |
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| | | *Umbilical, Embyonic, and Placental Cells".* | |
| 410 | MEX-139 | Mesnage R, *et al*., "*Cytotoxicity on human cells of Cry1Ab and Cry1Ac Bt insecticidal toxins alone or with a glyphosate-based herbicide."* | This section of Mexico's Initial Submission refers to "the presence of GMOs and glyphosate residues," but this study does not even study the amount of glyphosate residues on plants, much less GE corn. |
| 410 | MEX-208 | Xu, J., Smith, S., Smith, G., Wang, W. y Li, Y. "*Glyphosate contamination in grains and foods: An overview*". | This is a review of glyphosate generally, and corn grain is not listed in the table of glyphosate residues.[44] |
| 410 | MEX-313 | LEISA. *"Glyphosate in wheat, oats and beans."* | This short web article is highly emotive and displays significant bias. For example, this article uses words such as "food soaked in poison," "silent genocide," "accomplices" such as Argentine government agencies "turn[ing] a blind eye," and use of glyphosate "for greed and to sell more and faster." This article does not follow any standard journal practices and does not include proper citations to other research. |
| 410 | MEX-314 | Rubio, F., Guo, E., & Kamp, L., "*Survey of glyphosate residues in honey, corn and soy products."* | This study expressly says that glyphosate residues were <u>not</u> detected on the corn (syrup) samples. (p. 7). No other type of corn sample was tested. |

MEX-312, major limitations include not characterizing the test substance properly, and experiments focused more on the formulation as opposed to the active ingredient. *Id.* at 27, 149-150 (Exhibit USA-163). For MEX-207, major limitations include a focus on adjuvants, as opposed to the active ingredient, and deficiencies in reporting of study data. *Id.* at 26, 141-142 (Exhibit USA-163). For MEX-193, major limitations include incomplete characterization of the test substances and unknown relevance of in vitro effects to in vivo effects. *Id.* at 21, 100-102 (Exhibit USA-163).

[44] This study, and other studies cited by Mexico, also reference the glyphosate degradate, aminomethylphosphonic acid ("AMPA"). AMPA has a lower toxicity profile than that of glyphosate, with any observed effects associated with AMPA exposure occurring at doses much higher than glyphosate, even well above maximum dose levels set for guideline studies known as limit doses that are typically too large to be considered relevant for human health risk assessment. *See, e.g.*, EPA, "Human Health Risk Assessment in Support of Registration Review," at 30 (Dec. 12, 2017) (reflecting 90-day rodent study of AMPA (MRID 00241351) where effects seen at 1200 mg/kg/day, which is above the limit dose of 1000 mg/kg/day, and 90-day non-rodent study (MRID 43334702), with no effects up to the highest dose tested (~300 mg/kg/day)) (Exhibit USA-164). Residues of AMPA in both wild-type and GE crops are consistently less than residues of glyphosate. As both toxicity and magnitude of residues of AMPA are less than those for glyphosate, any risk assessment for glyphosate is protective of AMPA exposures.

| PARAGRAPH | EXHIBIT | SOURCE TITLE | ANALYSIS |
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| | | *Journal of Environmental & Analytical Toxicology.* | |
| N/A | MEX-085, at 15-16 (citing Swanson et al. (2014)) | Swanson, NL, A. Leu, J. Abrahamson & B. Wallet. (2014). "Genetically Engineered Crops, Glyphosate and the Deterioration of Health in the United States of America," *Journal of Organic Systems*. 9(2): 6-37). | Mexico's "risk assessment" (MEX-085) presents an adaptation and modification of the information presented in Swanson et al. (2014) and purports to show a correlation between an increased incidence of certain diseases as reported in data from the U.S. Centers for Disease Control and Prevention against survey data on the planting of GE crops. However, the Swanson et al. report lacks any data that demonstrate that the people that reported these diseases also were exposed to glyphosate (*e.g.*, in proximity to areas during glyphosate applications, from exposure to food, et cetera). |