MEXICO – MEASURES CONCERNING GENETICALLY ENGINEERED CORN

(MX-USA-2023-31-01)

RESPONSES OF THE UNITED STATES TO WRITTEN QUESTIONS FROM THE PANEL

July 15, 2024

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TABLE OF ABBREVIATIONS

Abbreviation	Definition
2023 Corn Decree or Decree	*Decree Establishing Various Actions Regarding Glyphosate and Genetically Modified Corn* [1]
ALOP	Appropriate level of protection
APHIS BRS	Animal and Plant Health Inspection Service, Biotechnology Regulatory Services
Biosafety Law	*Biosafety Law of Genetically Modified Organisms* (Feb. 2005)
Biosafety Regulations	*Regulations to the Genetically Modified Organisms Biosafety Law* (2008)
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"
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization of the United Nations
FDA	U.S. Food & Drug Administration

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

GE	Genetically engineered
IPPC	*International Plant Protection Convention*
MRL	Maximum residue level
Party	USMCA Party
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*

TABLE OF EXHIBITS

Exhibit No.	Description
USA-305	EPA, "Review of the Application for a FIFRA Section 3 Seed Increase Registration of MON 95379 Corn Expressing Transgenic Insecticidal Plant-Incorporated Protectants *Bacillus thuringiensis* Cry1B.868 and Cry1Da_7 Proteins and associated FFDCA Petition to Establish a Permanent Exemption from the Requirement of a Tolerance for Residues of Cry1B.868 and Cry1Da_7 Proteins when used as Plant-Incorporated Protectants in Food and Feed Commodities of Corn," (May 2024), https://www.regulations.gov/document/EPA-HQ-OPP-2020-0547-0004.
USA-306	U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services, "Pioneer Petition (19-101-01p) for Determination of Nonregulated Status for Enhanced Grain Yield Potential and Glufosinate-ammonium Resistant DP202216 Maize, Plant Pest Risk Assessment" (Sept. 2020), https://www.aphis.usda.gov/biotechnology/legacy-petition-process/petitions.
USA-307	Panel Report, *Japan – Measures Affecting the Importation of Apples – Recourse to Article 21.5 of the DSU by the United States*, WT/DS245/RW (adopted 20 July 2005).
USA-308	Mainon A. Schwartz, Congressional Research Service, "The 574 Federally Recognized Indian Tribes in the United States" (Jan. 2024), https://crsreports.congress.gov/product/pdf/R/R47414.
USA-309	Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments" (Nov. 6, 2000), https://www.govinfo.gov/content/pkg/FR-2000-11-09/pdf/00-29003.pdf.

1. The United States takes note of the Panel's instruction for Parties to elaborate as appropriate on the answers to the "Day 1 Questions" that the Parties addressed on Day 2 of the Hearing, and specifically the Panel's instruction to "not repeat the answers given during Day 2 of the Hearing." Accordingly, the United States provides the following responses to supplement—and therefore to be considered in conjunction with—the responses already given on Day 2 with respect to questions directed, at least in part, to the United States. Consistent with the Panel's instructions, the United States also provides brief responses to supplement oral comments regarding Questions 7 and 17 directed to Mexico.

I. "DAY 1 QUESTIONS" ADDRESSED ON DAY 2 OF THE HEARING

Question 1 (Mexico): Which specific documents in the record provide contemporaneous evidence of the internal preparatory process and considerations that led to the enactment of the 2023 Decree? The panel is aware of the contents of the 2020 Decree (USA-92); the 2020 Federal Law for the Promotion and Protection of Native Corn (MEX-12); the 2020 Dossier on glyphosate and GM crops (MEX-85); and the SNIB Database. Please identify any other documents, dated before the 2023 Decree, which evidence relevant procedures, considerations, and/or the weighing of potential policy alternatives.

Question 2 (All Parties): Is there any GM corn consumed directly by humans in the US, Mexico and Canada, other than for industrial use such as corn syrup, corn starch?

2. In light of the complete response provided by the United States at the hearing with the Panel, the United States does not wish to elaborate at this time on its comments provided during the hearing.

Question 3 (United States): Mexico's position is that "in the United States, after harvesting corn, GM corn is not labeled, separated or differentiated from non-GM corn." (MEX IWS, para. 111, citing MEX-95) What is the US's position on this assertion?

3. In light of the complete response provided by the United States at the hearing with the Panel, the United States does not wish to elaborate at this time on its comments provided during the hearing.

Question 4 (Mexico): Is there any type of Consumer Information in place/envisaged for GM/non-GM corn for human consumption?

Question 5 (United States): In its Rebuttal, Mexico has introduced an example of a new authorization with the restrictive end use language. (MEX Rebuttal, para. 448, citing MEX-405) Does the US acknowledge that Mexico has issued new authorizations for animal feed and industrial use?

4. In light of the complete response provided by the United States at the hearing with the Panel, the United States does not wish to elaborate at this time on its comments provided during the hearing.

Question 6 (Mexico): With respect to the Gradual Substitution measure, Mexico says on page 8 of its Opening remarks that "there is no regulatory or administrative mechanism capable of beginning to carry out a 'gradual substitution', and none is possible in the foreseeable future." If the latter is correct – if there really is no plan for acting on these provisions – then what was the purpose of including Articles 7 and 8 in the 2023 Decree?

Question 7 (Mexico): Since the 2023 Decree has been handed down, what actions are "the agencies and entities" carrying out "in order to conduct the gradual substitution" or the additional "relevant scientific studies" referenced in Article 8? Can Mexico confirm what it stated today, that any actions to implement Article 7 were "conditional" on first completing a risk assessment? Does Article 7 of the 2023 Decree essentially prejudge the outcome of the risk assessment that is yet to come, by concluding that substitution eventually will be called for? If the risk assessment suggests that substitution is not warranted, would a further Presidential Decree be required to undo Article 7?

U.S. Supplemental Response:

5. The United States emphasizes that the Substitution Instruction is a final adopted law with a clear dictate to substitute GE corn with non-GE corn. Mexico's belated argument that the Substitution Instruction is nothing more than a neutral call to engage in scientific inquiry is belied by the clear text of the measure itself.

6. Article 7 of the Substitution Instruction, as provided in this presidential decree, establishes that the relevant agencies "*will carry out* the appropriate actions *in order to conduct the gradual substitution* of genetically modified corn" (emphasis added). The Substitution Instruction mandates substitution and preordains the outcome. It is not neutral.

7. Indeed, to the extent the Substitution Instruction permits authorizations, it explicitly does so only "[u]ntil the substitution . . . *is achieved*."[2] Again, the measure expressly states that achieving substitution is the prescribed outcome.

8. While the exact timing of when to take the "appropriate actions" under the Substitution Instruction is left to the discretion of the implementing agencies, whether to take the actions to achieve substitution is not. 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.[3]

9. Mexico's arguments that it will conduct studies in the future (though there is no evidence of steps taken to perform such studies in the more than one year since the measure was adopted)

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[2] *Decree Establishing Various Actions Regarding Glyphosate and Genetically Modified Corn* ("2023 Corn Decree"), art. 7 (emphasis added) (Exhibit USA-3).

[3] 2023 Corn Decree, art. 10 (Exhibit USA-3).

provide no legal defense to Mexico's breaches of the SPS Chapter; indeed, they underscore them.

> **Question 8 (Mexico):** To the extent that Mexico invokes "food security and self-sufficiency" as among the objectives for which the 2023 Decree was introduced, are those permissible considerations for measures under Article 9.2 of the USMCA?
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> **Question 9 (United States & Mexico):** Mexico contends that there is an "indissoluble" relationship between glyphosate and GM corn. Does Mexico contend that all GM corn offered for export to Mexico has been treated with glyphosate, such that residues of that treatment may remain. Cf. the 2020 Dossier cites a 2017 study which would seem to suggest that there is a considerable portion of GM corn used for food that does not contain glyphosate. Can the category of 'GM corn' really be used as a shorthand for 'glyphosate-treated corn'? (MEX IWS, ¶ 314, citing MEX-85, PDF p. 9 referring to MEX-125) Are there any studies in the record that attempt to examine the human health impacts of the consumption of GM corn isolated from any issue of glyphosate risk – that is, of GM corn that has been confirmed not to contain glyphosate residues?

10. Mexico stated during the hearing that it would provide the Panel with a full list of studies relevant to this question as part of its written responses. The United States will comment on the response Mexico submits. Accordingly, the United States does not wish to elaborate at this time on its comments provided during the hearing.

> **Question 10 (United States & Mexico):** Is the determination of an ALOP entirely a subjective exercise by the Member (in the sense that it can "deem appropriate" any level of protection it wishes, in the language of Annex A.5 of the SPS Agreement), or is there also some requirement of objective reasonableness? Is there any limit to what a Member may unilaterally "deem appropriate" - and any role for a Panel other than determining what a Member itself has so "deemed"? Please refer to relevant jurisprudence and literature on record regarding the discretionary nature of ALOP.

U.S. Supplemental Response:

11. The United States recognizes that it is a Party's right to set what it deems to be the appropriate level of protection ("ALOP") for a particular risk to human, animal, or plant life or health. This is expressly recognized in Article 9.6.4(a) of the USMCA,[4] and is also consistent

[4] *See* USMCA, art. 9.6.4(a) ("Recognizing the Parties' rights and obligations under the relevant provisions of the SPS Agreement, this Chapter does not prevent a Party from . . . establishing the level of protection it determines to be appropriate.").

with the WTO SPS Agreement, whose definition of ALOP has been incorporated into and made part of the USMCA SPS Chapter.[5]

12. However, as past WTO dispute settlement reports have explained, "[t]he right of a Member to define its appropriate level of protection is not [] an absolute or unqualified right."[6] The USMCA and SPS Agreement are clear that a Party must still comply with its other obligations, including the obligation to base SPS measures either on relevant international standards, where these standards can meet the Party's ALOP, or on a risk assessment,[7] and to adopt measures that are no more trade restrictive than required to achieve a Party's ALOP.[8] Similarly, the risk must be ascertainable; a Party cannot simply rely on theoretical uncertainty.[9] In other words, if a Party asserts "zero risk" as its ALOP, as Mexico has done, that does not mean a Party can presumptively ban a substance. A Party must nevertheless conduct a risk assessment, as it would with any other ALOP, to demonstrate why the measure is necessary and, moreover, not more-trade restrictive than necessary to achieve that ALOP.

> **Question 11 (United States & Mexico):** What conclusions should the Panel draw from the fact that the 2020 Decree did refer directly to the precautionary principle while the 2023 Decree does not? To the extent that Mexico relies on the precautionary principle for either Measure, what factual findings would the Panel first need to make regarding (a) the sufficiency of scientific evidence, (b) the conduct of a risk assessment based on the evidence thus far on the case record, (c) the timeframe for those studies, and (d) the

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[5] USMCA, art. 9.1.1; *see also, e.g.*, Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, para. 172 (adopted Feb. 13, 1998) ("The right of a Member to determine its own appropriate level of sanitary protection is an important right.") (hereinafter "Appellate Body Report, *EC – Hormones*") (Exhibit USA-250); Panel Report, *Japan – Measures Affecting the Importation of Apples – Recourse to Article 21.5 of the DSU by the United States*, WT/DS245/RW, para. 8.193 (adopted 20 July 2005) ("We first recall that it is for Japan to determine its ALOP, and that we should not question it.") (Exhibit USA-307).

[6] Appellate Body Report, *EC – Hormones*, para. 173 (Exhibit USA-250).

[7] USMCA, art. 9.6.3; SPS Agreement, art. 3.3 (Exhibit USA-34); *see also* Appellate Body Report, *EC – Hormones*, para. 177 ("[C]ompliance with Article 5 .1 [providing that Members shall ensure SPS measures are based on an appropriate risk assessment, taking into account risk assessment techniques of relevant international organizations] was intended as a countervailing factor in respect of the right of Members to set their appropriate level of protection.") (Exhibit USA-250).

[8] USMCA, art. 9.6.10; SPS Agreement, art.5.6 (Exhibit USA-34).

[9] Appellate Body Report, *EC – Hormones*, para. 186 (Exhibit USA-250) (noting that science can never provide absolute certainty that a given substance will never have adverse health effects); Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, para. 125 (adopted Nov. 6, 1998) (explaining that "the 'risk' evaluated in a risk assessment must be an ascertainable risk; theoretical uncertainty is 'not the kind of risk which, under Article 5.1, is to be assessed,'" quoting *EC – Hormones*) (Exhibit USA-109).

reasonableness or adequacy of such risk assessment? Please refer, inter alia, to Article 9.6.5 of the USMCA.

13. In light of the complete response provided by the United States at the hearing with the Panel, the United States does not wish to elaborate at this time on its comments provided during the hearing.

Question 12 (United States & Mexico): Please explain why the Codex Principles and Guidelines and the IPPC are sufficient/insufficient to qualify as relevant international standards, guidelines, or recommendations for GM corn?

U.S. Supplemental Response:

14. Codex and IPPC are the relevant standard-setting bodies for food safety and plant health, respectively, and are recognized as such expressly in the USMCA.[10]

15. To begin with food safety, paragraph 3(a) of Annex A of the SPS Agreement, incorporated into the USMCA, affirms that the Codex standards relating to "food additives, . . . pesticide residues, [and] contaminants," are the relevant international standards for assessing the safety of food. In this dispute, Mexico claims that both transgenes and pesticide residues would be a "contaminant,"[11] and alleges various other safety and nutritional concerns related to human consumption of GE corn.[12]

16. The Codex *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* ("Codex Principles") are directly on point, outlining a case-by-case (*i.e.*, event-specific) premarket risk assessment to evaluate the "safety and nutritional aspects of foods derived from modern biotechnology" vis-à-vis appropriate conventional counterparts.[13] The Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* ("Codex Guidelines") further elaborate on the food safety assessment process for foods derived from GE plants.[14] Mexico's own regulatory authority responsible for

[10] USMCA, art. 9.1.2 (incorporating by reference the SPS Agreement's definition of "relevant international standards, guidelines, or recommendations").

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

[12] *See, e.g.*, Mexico's Initial Submission, Section V.D.1.b.

[13] Exhibit USA-113.

[14] Exhibit USA-114.

assessing the safety of GE events (COFEPRIS) has confirmed that Codex provides the relevant standards applicable to safety assessments of GE foods.[15]

17. Had Mexico actually followed the Codex standards, and its own Biosafety Law and Regulations,[16] Mexico would have evaluated the very risks that it purports to be of concern; instead, Mexico has disclaimed the relevance of these standards—and, in effect, its own regulations—and put forward a so-called "risk assessment" that does not assess risks in a manner consistent with the USMCA.[17]

18. As the Codex Guidelines make clear, whole-food animal feeding studies of the sort that Mexico has heavily cited in its submissions are not typically relied upon in assessing the risks of GE crops and other foods due to confounding variables and difficulties of interpreting such data.[18] Instead, a multidisciplinary approach is used that takes into account both intended and unintended changes that may occur in the plant or in the foods derived from it.[19]

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[15] Food and Agriculture Organization of the United Nations ("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).

[16] *See Law on Biosafety of Genetically Modified Organisms* ("Biosafety Law"), art. 9(VIII) (Feb. 2005) ("The possible risks that GMOs activities may entail to human health and biological diversity will be evaluated case by case. Such assessment must be supported by the best scientific and technical evidence available.") (Exhibit USA-85); *Regulations to the Genetically Modified Organisms Biosafety Law* (2008) ("Biosafety Regulations"), arts. 31-32 (providing that a "[s]tudy of potential risks that the human use or consumption of the GMO in question may represent to human health, which shall include scientific and technological information about its safety, [] shall include the following") (Exhibit USA-86).

[17] *See* U.S. Rebuttal Submission, Section IV.A.

[18] Mexico disproportionately cites to whole-food animal feeding studies, which are considered to be the least reliable for assessing food safety and thus studies of last resort. *See, e.g.*, MEX-126, MEX-129, MEX-131, MEX-132, MEX-136, MEX-225; *see also* Report of Michael Antoniou (citing almost exclusively to whole-food animal feeding studies). A whole-food study involves feeding animals, typically rodents, high levels of certain foods with the intent of evaluating whether the food has any toxicological effects at the doses provided. As far back as 2003, it was clear that such studies had significant limitations. *See* Codex Guidelines, paras. 11-12 (Exhibit USA-114) ("Animal studies cannot readily be applied to testing the risks associated with whole foods, which are complex mixtures of compounds, often characterised by a wide variation in composition and nutritional value. . . . In addition, a key factor to consider in conducting animal studies on foods is the nutritional value and balance of the diets used, in order to avoid the induction of adverse effects which are not related directly to the material itself. Detecting any potential adverse effects and relating these conclusively to an individual characteristic of the food can therefore be extremely difficult."). Even if one were to assume that the cited studies were accurate, Mexico has not taken the results and conducted the actual risk assessment required, evaluating hazard, exposure, and risk, to fulfill its commitments under the USMCA.

[19] Codex Guidelines, para. 11 (Exhibit USA-114). Furthermore, as the Codex Guidelines point out, the potential occurrence of unintended effects is not unique to genetic engineering: "Rather, it is an inherent and general

19. As the Codex Guidelines explain, "the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA plants" is to identify similarities and differences between the new food and its conventional counterpart, to help identify potential safety and nutritional issues. This approach focuses on assessing the safety of any identified differences so that the safety of the new product can be considered relative to its conventional counterpart.[20]

20. In practice, a risk assessment for food derived from GE plants, as provided under the Codex Guidelines and reflected in Mexico's Biosafety Regulations, contains five main parts:

(i) A description of the particular GE event;[21]

(ii) An assessment of possible toxicity;[22]

(iii) An assessment of possible allergenicity;[23]

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phenomenon that can also occur in conventional breeding. Unintended effects may be deleterious, beneficial, or neutral with respect to the health of the plant or the safety of foods derived from the plant." The Codex risk assessment process includes methods to identify and detect such unintended effects and procedures to evaluate their biological relevance and potential impact on food safety. *See* Codex Guidelines, paras. 14-17 (Exhibit USA-114).

[20] Codex Guidelines, para. 12 (Exhibit USA-114). Mexico has cited various studies in its submission, alleging that certain GE varieties are not "substantially equivalent" to their conventional counterparts. The concept of "substantial equivalence" is not an appropriate metric in itself for assessing food safety and is not the standard that the United States uses. *Contra* Mexico's Rebuttal Submission, paras. 82, 378 (claiming that the United States uses a substantial equivalence standard); Report of Michael Antoniou, paras. 10, 45, 86-88 (referring to substantial equivalence). Substantial equivalence is only a step in the safety assessment process and not an endpoint. *See* Codex Guidelines, para. 13 (Exhibit USA-114) ("The concept of substantial equivalence . . . is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart."). Of the chemicals in foods, many could change concentrations and not raise safety or nutritional concerns. Consequently, it is possible to have a food that is not "substantially equivalent" to its conventional counterpart but is still safe. More appropriately, the United States, consistent with Codex, uses a comparative approach that compares important safety and nutritional characteristics between the new plant and its conventional counterpart and, taking this and other relevant information into consideration, asks whether the new food is safe under the conditions of its intended use. This assessment will necessarily be specific to the type of food under review, and Mexico has pointed to no study with respect to GE corn that has raised any legitimate safety or nutritional concern.

[21] *See* Codex Guidelines, sec. 4 (Exhibit USA-114).

[22] *See* Codex Guidelines, paras. 34-40 (Exhibit USA-114).

[23] *See* Codex Guidelines, paras. 41-43 (Exhibit USA-114); *see also id.*, Annex 1 ("Assessment of Possible Allergenicity") (Exhibit USA-153).

(iv) A compositional analysis of key components;[24] and

(v) Other considerations such as the potential accumulation of pesticide residues and the use of antibiotic resistance marker genes.[25]

21. The first step (description of the particular GE event) involves, *inter alia*, describing the particular gene or genes being presented for a safety assessment and the type and purpose of the modification; information on each donor and the recipient organism; an evaluation of the introduced genetic material, including its location and arrangement; characterization of each genetic component (including marker genes, promoters, and terminators that have any effect on DNA function[26]); an assessment of the stability of the genetic modification over multiple generations (including under processing conditions); and any information that suggests that one or several genes in the host plant are affected by the transformation process.[27]

22. The next step in the risk assessment process is an evaluation of the possible toxicity of expressed substances. As part of this step, one should identify the concentration of the substance in the edible parts of the plant. As Codex specifies, current dietary exposure of relevant populations should be considered.[28] Mexico's Biosafety Regulations already require a comprehensive set of toxicology studies, covering severe toxicity, sub-chronic toxicity, chronic toxicity, and, where the GE events are intended for food or food processing (as relevant here), studies specifically on the food constituents or any specific components that may undergo changes due to the genetic modification.[29]

23. The third step in assessing risks from foods derived from GE plants is an assessment of possible allergenicity of any newly expressed proteins that could be present in the final food. Again, this should be done on a case-by-case basis and using sound scientific methods and

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[24] *See* Codex Guidelines, paras. 44-45 (Exhibit USA-114); *cf. id.*, para. 48 & Annex 2 (concerning GE crops that have undergone modifications to intentionally alter nutritional quality or functionality, which are subject to an additional nutritional assessment) (Exhibits USA-114, USA-153).

[25] Codex Guidelines, paras. 18, 54-58 (Exhibit USA-114).

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

[27] *See* Codex Guidelines, paras. 22-33 (Exhibit USA-114); Biosafety Regulations, art. 31(I)(a)-(i) (Exhibit USA-86).

[28] *See* Codex Guidelines, paras. 34-35 (Exhibit USA-114). As Codex explains, if a substance has historically been consumed safely in food, taking into account its function and exposure levels, then toxicology studies may not be necessary.

[29] *See* Biosafety Regulations, art. 31(I)(l) (Exhibit USA-86).

principles.[30] The relevant exposure level to the newly expressed protein and the effects of any relevant food processing must be considered in reaching an overall conclusion about the potential for human health risk.[31] Mexico, pursuant to its Biosafety Regulations, has traditionally required a thorough examination of allergenicity with respect to any GE corn event seeking authorization.[32]

24. Next, compositional analysis of key components of the GE plant is required and should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. As the Codex Guidelines explain, the statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance.[33] This approach ensures that any observed differences are scientifically justified and within the range of variation typically found in conventionally bred organisms that have a long history of safe use. Mexico, in its existing authorization process, requires studies that demonstrate the safety of key components in the GE crop based on use and consumption conditions in Mexico (including Mexico-specific chronic consumption data) whenever the GE event is intended for use as a foodstuff or intended for food processing.[34]

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[30] *See* Codex Guidelines, paras. 20, 41 (Exhibit USA-114); Codex Guidelines, Annex 1 ("Assessment of Possible Allergenicity") (USA-153).

[31] Codex Guidelines, Annex 1, para. 16 (USA-153). The Codex Guidelines further provide that "the potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants" should be considered throughout all stages of the risk assessment process. *See* Codex Guidelines, para. 47 (Exhibit USA-114).

[32] Pursuant to Mexico's Biosafety Regulations, applicants must provide complete allergenicity studies, which include information on the origin of genetic material, homology with known allergens, effects of pH and enzymatic digestion, stability against temperature, post-transduction modifications, and Immunoglobulin E ("IgE") cross-reactivity analysis when potential allergenicity is indicated. *See* Biosafety Regulations, art. 31(I)(m) (Exhibit USA-86).

[33] Codex Guidelines, para. 44 (Exhibit USA-114). In its submissions, Mexico cites numerous "omics" studies that purport to show biochemical changes within the GE plants that differ from the non-GE comparator. *See, e.g.*, MEX-135, MEX-143, MEX-144, MEX-145, MEX-146. These studies simply found that biochemical changes occurred in the plant (as compared to its isoline, *i.e.,* the otherwise identical twin plant) after the genetic modification. What these studies did not find is any basis for believing these biochemical changes could potentially adversely affect human, animal, or plant life or health. In other words, the observed changes, indeed any biochemical change, are only relevant if you can hypothesize some plausible pathway to an adverse consequence as a result of the observed biochemical change. These studies did not. That is not surprising, since the same types of genetic changes Mexico is pointing to in these studies can and do also occur from traditional breeding. A more appropriate evaluation is to look at the genetic variation in a crop plant and assess the GE plant within that genetic variability. If there is an unusual genetic or biochemical change resulting from the genetic engineering that has not been seen previously within the existing genetic variability of that plant crop, a scientist will require more information and investigate further whether there is a plausible pathway by which the biochemical change could pose a health risk.

[34] *See* Biosafety Regulations, art. 31(I)(j)(5) (Exhibit USA-86); *see also* U.S. Rebuttal Submission, paras. 159-160.

25. Finally, a risk assessment of GE plants intended for food use includes consideration of other potentially relevant issues, such as the potential accumulation of pesticide residues or the use of antibiotic resistance marker genes.[35] For example, some GE events may display traits that could indirectly result in the potential accumulation of pesticide residues, and such accumulation should be taken into account using conventional procedures for assessing the human safety of chemicals.[36] This means evaluating any relevant toxicity, residue, and exposure data to ascertain the safety of any pesticide residues of concern, consistent with conventional dietary risk assessment procedures.[37]

26. It should also be noted that the Codex Guidelines apply whether the GE crop is comprised of one or multiple (*i.e.*, "stacked") GE traits. Indeed, Mexico's existing authorization process requires that an applicant apply anew whenever it seeks to market a stacked GE product. Mexico's Biosafety Regulations require that an applicant provide a risk assessment that includes scientific information on the parental events, which must have been previously authorized in Mexico, and assess potential interactive effects of the combined genes.[38]

27. To help illustrate how a methodical, scientifically sound human health risk assessment of a GE event is performed in practice, consistent with the Codex Guidelines and the USMCA, the United States provides, for reference purposes, an example from the U.S. regulatory process.[39]

28. With respect to plant health risk, as distinct from human health, the United States reiterates that the IPPC standards, recognized as the relevant standards under the USMCA for

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[35] Codex Guidelines, paras. 18, 54-58 (Exhibit USA-114).

[36] Codex Guidelines, para. 54 (Exhibit USA-114).

[37] *See also, 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 a dietary risk assessment evaluates risks to human health resulting from pesticide residues in or on food) (Exhibit USA-249).

[38] *See* Biosafety Regulations, art. 31(I)(n) (Exhibit USA-86). These "stacked" trait products are typically developed through conventional cross-breeding of GE parental plants. The United States is not aware of any safety assessments concluding that stacked GE traits through conventional breeding pose any greater risk to food or feed safety than stacking multiple non-GE traits by conventional breeding. In addition, contrary to statements by Mexico (*e.g.*, Mexico's Rebuttal Submission, paras. 24, 31; Report of Michael Antoniou, paras. 17, 27, 32, 35-36, 45, 100), the U.S. regulatory process examines the potential for interactive effects (synergy, antagonism, or additive effects) when two or more plant-incorporated protectants ("PIPs") are in the same plant; this evaluation is conducted through a mandatory premarket process, as this combination would represent a new pesticide mixture.

[39] *See, e.g.*, EPA, "Review of the Application for a FIFRA Section 3 Seed Increase Registration of MON 95379 Corn Expressing Transgenic Insecticidal Plant-Incorporated Protectants *Bacillus thuringiensis* Cry1B.868 and Cry1Da_7 Proteins and associated FFDCA Petition to Establish a Permanent Exemption from the Requirement of a Tolerance for Residues of Cry1B.868 and Cry1Da_7 Proteins when used as Plant-Incorporated Protectants in Food and Feed Commodities of Corn" (May 2024), https://www.regulations.gov/document/EPA-HQ-OPP-2020-0547-0004 (Exhibit USA-305).

plant health, are directly apposite to GE corn and any associated concerns about damage caused to other plants from transgenic introgression. The IPPC's *International Standard for Phytosanitary Measures 11* ("ISPM 11") lays out a pest risk assessment framework directed at living modified organisms—*i.e.*, plant organisms that are the product of modern biotechnology.[40] The IPPC standards, and the ISPM 11 in particular, outline the process for assessing the entry, establishment, and spread of a potential plant pest by identifying the potential pathways of the pest, specific to the genes or traits of concern.[41]

29. The IPPC standards are not specific to a particular kind of agriculture but rather provide a framework to methodologically assess whether a plant pest risk exists and the potential or actual harm such as disease or injury to other plants, which includes an assessment of economic and environmental impacts.[42] Mexico has not presented any document or documents that would remotely conform to the IPPC standards; however, to help illustrate how a methodical, scientifically sound plant pest risk assessment is performed in practice, the United States provides, for reference purposes, an example from the U.S. regulatory process.[43]

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[40] *See* Secretariat of the IPPC, *Pest Risk Analysis for Quarantine Pests* ("ISPM 11"), sec. 3.4.6 (2017), https://www.ippc.int/static/media/files/publication/en/2017/05/ISPM_11_2013_En_2017-05-25_PostCPM12_InkAm.pdf (Exhibit USA-103).

[41] ISPM 11, sec. 2.1.1.1 ("In the case of [living modified organisms ("LMOs")], identification [of the pest] 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).

[42] *See* ISPM 11, secs. 2.1-2.5 (Exhibit USA-103); *see also* Secretariat of the IPPC, *Framework for Pest Risk Analysis*, sec. 2.2 (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).

[43] *See, e.g.*, U.S. Department of Agriculture ("USDA"), Animal and Plant Health Inspection Service, Biotechnology Regulatory Services ("APHIS BRS"), "Pioneer Petition (19-101-01p) for Determination of Nonregulated Status for Enhanced Grain Yield Potential and Glufosinate-ammonium Resistant DP202216 Maize, Plant Pest Risk Assessment" (Sept. 2020), https://www.aphis.usda.gov/biotechnology/legacy-petition-process/petitions (Exhibit USA-306). In performing the plant pest risk assessment, the agency assesses whether the plant can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product and whether the GE plant would pose an increased plant pest risk as compared to non-GE comparators. *See* U.S. Code of Federal Regulations, Title 7, Part 340 ("Movement of Organisms Modified or Produced Through Genetic Engineering"), https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-340 (Exhibit USA-80); *see also* ISPM 11, at 22 ("For LMOs, the acceptable level of risk may also be expressed by comparison to the level of risk associated with similar or related organisms, based on their characteristics and behaviour in a similar environment to the PRA area.") (Exhibit USA-103). USDA assesses not only the data and information provided by an applicant seeking to bring this crop variety to market but also the relevant scientific literature available. There is no trait that USDA has deregulated that has been considered to pose a plant pest risk to another corn variety or other sexually compatible relative. All GE corn events that have been authorized in Mexico have been assessed and assigned deregulated status in the United States, *i.e.*, were found not to present an increased plant pest risk relative to its conventional comparators. Mexico likewise can and must conduct a risk assessment for any "pest" that it claims in these proceedings presents a risk to plant life or health in Mexico.

Question 13 (Mexico): To the extent that the evidence shows one principal motivation for the 2023 Decree was a concern about potential glyphosate residues, are Articles 6 and 7 appropriately targeted to that concern (given that they would seem to apply also to GM corn not exposed to glyphosate)? Was consideration given to a more targeted measure?

Question 14 (All Parties): Were the US, Canada and "other Parties and persons of the Parties" invited to comment on the 2023 Decree prior to its adoption?

30. In light of the complete response provided by the United States at the hearing with the Panel, the United States does not wish to elaborate at this time on its comments provided during the hearing.

Question 15 (All Parties): What do the Parties contend must be provided for comment under Article 9.6.7: particular scientific studies, a complete risk assessment, or a proposed state measure relying on those studies?

31. In light of the complete response provided by the United States at the hearing with the Panel, the United States does not wish to elaborate at this time on its comments provided during the hearing.

Question 16 (United States & Mexico): Do you agree that "benefits" can be "direct" or "indirect" in the present case? Does this cover both violation and non-violation complaints? In the answer, please refer to chapeau sub-paragraphs 1(a) and 1(b) and to the text of GATT Article XXIII:1, and WTO rulings relevant for the case at hand.

U.S. Supplemental Response:

32. In addition to the response already provided during the hearing, the United States observes that the "benefit" in Article 31.2(c) is characterized neither as a "direct" or "indirect" benefit, but rather one "it could reasonably have expected to accrue." The directness of a benefit may therefore have some relevance as to whether a Party could reasonably have expected it to accrue.

Question 17 (Mexico): There has been no further discussion of this article in recent submissions; does the Panel still need to decide any issues under this article?

U.S. Supplemental Response:

33. In the U.S. Rebuttal Submission, the United States asserted that Article 24.15.2 does not operate as an exception that provides an affirmative defense to breaches of other provisions of the USMCA and, accordingly, has no legal relevance to resolving this dispute. Mexico has not opposed this assertion.

Question 18 (United States & Mexico): Can Article XX of the GATT 1994 be invoked where a Panel finds no inconsistency with the SPS Agreement? Does the *mutatis*

mutandis language in Article 32.1.1 of the USMCA suggest any different application of Article XX of the GATT 1994 under the USMCA than under the WTO/DSU?

34. In light of the complete response provided by the United States at the hearing with the Panel, the United States does not wish to elaborate at this time on its comments provided during the hearing.

Question 19 (United States): Are there any "Indigenous Peoples' Rights" issues relevant for GM products in the US?

U.S. Supplemental Response:

35. Please see the United States' response to Final Panel Question Number 5, *infra*, with regard to Indigenous Peoples and GE products.

Question 20 (Mexico): What specific legal obligations to indigenous peoples does the 2023 Decree fulfill?

Question 21 (Canada): **For Canada**: Are there any Indigenous Peoples' Rights" issues relevant for GM products in Canada?

Question 22 (United States & Mexico): With reference to Article 31.13.4 of the USMCA, what "customary rules of interpretation of public international law, as reflected in Articles 31 and 32" of the VCLT do the Parties consider relevant in this case?

36. In light of the complete response provided by the United States at the hearing with the Panel, the United States does not wish to elaborate at this time on its comments provided during the hearing.

Question 23 (United States): Please elaborate why the 2023 Decree nullifies or impairs the benefits of the USMCA? Please also refer to Article 32.5.

37. In light of the complete response provided by the United States at the hearing with the Panel, the United States does not wish to elaborate at this time on its comments provided during the hearing.

Question 24 (Mexico): If the Panel were to make a determination that the US's benefits under the USMCA are nullified or impaired, could the 2023 Decree be modified to avoid nullification and impairment?

Question 25 (All Parties): Do the Parties contend that any of the issues that the Panel will be called upon to decide require determinations of technical or scientific facts that are contested in this case; if so, (a) identify the contested technical or scientific facts which they contend require determination, and (b) indicate whether the Parties believe

such determinations would be assisted by the appointment of an expert pursuant Article 31.15 of the USMCA and Article 23 of the Rules of Procedure?

38. In light of the complete response provided by the United States at the hearing with the Panel, the United States does not wish to elaborate at this time on its comments provided during the hearing.

II. FINAL PANEL QUESTIONS

Question 1 (United States & Mexico): Please confirm whether there is data on the volume of Mexico's imports of GM and non-GM corn in the years 2017-2023, including the breakdown of white and yellow corn, and if so, please provide such data.

39. The United States does not maintain data on the volume of U.S. corn exports to Mexico that are genetically engineered ("GE") versus non-GE, nor is the United States aware of any data in Mexico that would reflect this information.

Question 2 (Mexico): How much of the white corn produced in Mexico is classified as native corn (as defined in Article 2.VII of the Federal Law for the Promotion and Protection of Native Corn [MEX-12]), as opposed to domestically produced non-native corn? Please provide data for the years 2017-2023. Is there data that indicates how much of each category (native and non-native corn) is produced by indigenous peoples?

Question 3 (United States): In response to Question 9 of the Panel's Day 1 Questions, the US indicated that it would determine if there is data identifying the percentage of GM corn that has been treated with glyphosate. The Panel remains interested in such data if it is available. For avoidance of doubt, the Panel is not inquiring about the prevalence of traits that render corn glyphosate resistant, but about actual application of glyphosate.

40. Based on the data available, from 2017 through 2021, an estimated 90 percent of U.S. corn acreage was planted with herbicide-tolerant corn varieties, and the remaining 10 percent was planted with non-herbicide tolerant corn varieties.[44] Available usage data covering this time period indicate that, on average, approximately 80 percent of herbicide-tolerant corn acreage was treated with glyphosate annually, and 15 percent of non-herbicide tolerant corn acreage was treated with glyphosate annually.

[44] The data provided in response to Question 3 come from Kynetec, Inc. 2023, an agricultural market research service that is commonly accepted as a source of best available U.S. pesticide usage data. The term "herbicide-tolerant corn" is largely synonymous with transgenic corn, with a small number of exceptions (*e.g.*, some varieties grown in the United States are recognized as non-transgenic). Furthermore, during this time frame, the vast majority (over 99 percent) of herbicide-tolerant corn contained glyphosate-tolerant traits. Therefore, the estimated percent of glyphosate-tolerant and non-glyphosate tolerant corn treated with glyphosate is approximately equal to the values presented above for herbicide-tolerant and non-herbicide-tolerant corn.

41. In other words, during this time period, approximately 73.5 percent of all U.S. corn acreage was treated with glyphosate annually. Moreover, approximately 18 percent of all U.S. corn acreage was herbicide-tolerant corn varieties that were **not** treated with glyphosate.

> **Question 4 (Mexico):** Are there regulations in Mexico, which govern seed exchange as it pertains to corn?
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> **Question 5 (United States & Canada):** In response to Questions 19 and 21 of the Panel's Day 1 Questions, both the US and Canada indicated that they would consult further with the corresponding agencies and indicate if there were any indigenous rights issues related to GM products. The Panel remains interested if such information has been identified.

42. After consulting with federal government agencies, the United States is not aware of any Indigenous peoples' rights affected by its policies related to GE products.

43. The Indigenous peoples of the United States are predominantly American Indians and Alaska Native Peoples. The U.S. federal government recognizes and maintains government-to-government relations with 574 sovereign tribal nations. Of the 574 federally recognized tribal nations, 347 are located within the forty-eight contiguous states and 227 are located in Alaska.[45] Since its formation, the United States has recognized tribal nations as domestic dependent nations under its protection and has enacted numerous statutes and promulgated numerous regulations that establish and define a trust relationship with the tribal nations. Specifically, tribal nations in the United States are recognized as sovereign nations with inherent powers to self-govern their members and territory.

44. With the aim to strengthen the government-to-government relationships with American Indian and Alaskan Native Peoples, Executive Order 13175 of November 6, 2000, *Consultation and Coordination with Indian Tribal Governments*, sought to establish regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications. According to this Executive Order, "policies that have tribal implications" refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.[46] The U.S. federal government agencies that have policies related to the regulation of GE products, are not

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[45] Mainon A. Schwartz, Congressional Research Service, "The 574 Federally Recognized Indian Tribes in the United States" (Jan. 2024), https://crsreports.congress.gov/product/pdf/R/R47414 (Exhibit USA-308).

[46] *See* Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments" (Nov. 6, 2000), https://www.govinfo.gov/content/pkg/FR-2000-11-09/pdf/00-29003.pdf (Exhibit USA-309).

aware of any policies that would have "tribal implications" as articulated in Executive Order 13175.