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Comments on No. TPA-105-003, United States-Mexico-Canada Agreement: Likely Impact on the U.S. Economy and on Specific Industry Sectors

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Overview

The Institute for Agriculture and Trade Policy[1] (IATP) appreciates this opportunity to comment on aspects of the United States-Mexico-Canada Agreement (USMCA), and to assist the United States International Trade Commission (USITC) in completing the report required by Sec. 105. IATP last wrote to the USITC on February 16, 2016, regarding the proposed Trans-Pacific Partnership Agreement (TPPA).[2] Part of the following analysis on non-tariff measure impacts are drawn from this TPPA analysis, insofar as many of the provisions of the USMCA were derived from the TPPA.

Since its inception, the North American Free Trade Agreement (NAFTA) has been promoted as a means toward expanding U.S. agricultural exports, which presumably would result in a prosperous U.S. farm economy. The falling U.S. net farm income of the past five years cannot be reversed by U.S. agricultural policies designed to keep prices low, often below the cost of production, to "compete" with the same commodities from other major agricultural exporting countries. Unfortunately, with respect to agricultural policy, the USMCA continues the flawed approach of the original NAFTA. Changing trade policy to prevent U.S. agricultural export dumping will not by itself change U.S. agricultural policy to make it more market-based and less dependent on government payments. That change does not end with change to the terms of the USMCA, but it could begin there.

In the following comments, we first address a major flaw at the heart of the USMCA: Its failure to account for, and to address, the negative and sweeping impacts of climate change on the U.S. economy, especially on the agricultural sector. Next, we review the current state of the U.S. farm economy and the likely impact of the USMCA's overall approach, which fails to address the serious underlying weaknesses of the agricultural sector of economy, instead continuing the policies promoted in the original NAFTA. We then analyze several sections of the USMCA of particular concern: The provisions on agricultural biotechnology; the sanitary and phytosanitary chapter; intellectual property provisions relating to agricultural chemicals; sectoral annexes to the chapter on technical barriers to trade; and the chapter on good regulatory practices. We focus particularly on whether these provisions will protect and advance "the interests of United States consumers" in the context of the institutional capacity—or lack of capacity—of U.S. agencies to implement the terms of the USMCA.

The elephant in the room: Accounting for the climate change-related "likely impacts" of the USMCA to the whole U.S. economy

The USITC is required by law to distinguish the "likely impact of the agreement" from all the other factors that impact the economy of any sector. This is exceedingly difficult, as the USITC has noted in staff studies. For example, "Much of the literature cautions about attributing trade growth to NAFTA that may actually be the result of other factors discussed above (pre-NAFTA trade liberalization by Mexico, changes to Mexican agricultural policy, and macroeconomic and demographic changes and shocks in Mexico)."[3] Despite this caution, USITC will be under pressure to deliver a statistical basis for the "thumbs up" response given by U.S. agribusiness and commodity groups with farmer members even before the USMCA text was finalized.[4] Even if "likely impacts" are considered only in terms of trade flows, there is ample reason to continue to be cautious.

The "likely impacts" about "the economy as a whole" that the USITC are required to report are macro-economic and econometric projections dependent on policy scenarios. While the USITC will undoubtedly receive comments on the past growth in trade under NAFTA, these statistics can be misleading and incomplete. IATP does not have a macro-economic based growth comment on NAFTA but notes that part of the tripling of trade comprises intra-corporate supply chain exchange, rather than counting only trade in finished products. For example, the birthing and raising of two million beef cattle a year from Mexico and Canada for import to be fed out and slaughtered in the United States as U.S. labeled beef products is counted as a tri-national increase in trade, rather than trade under the control of one of four transnational meatpackers.[5] USITC should evaluate and report to Congress not just the claimed "modest but positive" macro-economic benefits of NAFTA,[6] but also its macro-economic and sector-specific costs, including those of creative trade accounting. In the case of this comment, that sector is agriculture and the rural economy.

The climate change impacts and costs of the USMCA are externalized in orthodox trade economics. The USMCA incentivizes increased trade in fossil fuels and their derivatives and authorizes private arbitration panels to challenge the necessity of regulatory measures affecting fossil fuel trade and investments.[7] The USITC should adapt the social cost of carbon emissions estimates now being used by federal states for long-term investment planning in public utilities[8] to estimating the social cost of fossil fuel trade among the United States, Mexico and Canada. If the USITC chooses not to use the social cost of carbon framework, it should at least estimate the impact of the renewable energies on the demand for cross-border fossil fuels.[9]

The USITC should apply the methodology of the *Fourth National Climate Assessment*, particularly Vol. II "Impacts, Risks and Adaptation in the United States," to the trade and investment impacts of the USMCA. A key message of the *Assessment* is: "The impacts of climate change,

variability, and extreme events outside the United States are affecting and are virtually certain to increasingly affect U.S. trade and economy, including import and export prices and businesses with overseas operations and supply chains."[10] However, the authors do not provide an empirical analysis that corresponds to this key message. The *Assessment* references the work of the National Oceanic and Atmospheric Administration to analyze "Transboundary Climate Related Impacts" for the United States, Canada and Mexico.[11]

The USITC should use the NOAA methodology of a multi-disciplinary, multi-sectoral research team to develop the outline for a "Transboundary Climate Related Impacts of USMCA" report. How will climate change affect individual economic sectors, supply chains and the financial and insurance industries that serve these sectors? If a complete analysis cannot be completed in the time allotted for this report, even a cautionary note from the USITC to Congress about the need to assess the trade-related costs (e.g. from climate change enhanced loss and damage), could promote a more realistic assessment of the USMCA. Otherwise, Congress will receive a highly distorted assessment of the likely impact of the USMCA on the whole economy, for example expanding trade in fossil fuels without estimating the climate-related costs of that trade.

Perhaps less evidently (as regarding climate change), the USMCA further entrenches tri-national Confined Animal Feed Operations (CAFOs) whose feed grain fertilizer and animal agriculture manure management practices are a major source of nitrous oxide and methane, respectively.[12] According to a July 2018 report by IATP and GRAIN, based on UN Food and Agriculture Organization emissions accounting methodology, "Together, the world's top five meat and dairy corporations are now responsible for more annual greenhouse gas emissions than ExxonMobil, Shell or BP."[13] Cargill, Tyson Foods, JBS and Dairy Farmers of America are the major agribusiness emitters who are also beneficiaries of and advocates for the tri-national CAFO agribusiness model.

Environmental Protection Agency research on the social cost of nitrous oxide and methane does not have the degree of economic acceptance as does its work on the social cost of carbon dioxide emissions.[14] However, as the main U.S. feed grain exports become more climate vulnerable under climate change[15], any measure of the "likely impacts" of the USMCA in agriculture and other sectors must take into account the "Business As Usual" scenarios for increased GHG emissions and the decreasing time and resources to robustly adapt to climate change-related loss and damage. A 2018 study estimated that regardless of the Trump administration's downward revision of the social cost of carbon emissions, the United States will suffer more loss and damage from climate change than any other country, save India.[16] One of the study's authors said, "American policy is looking backward to a world that no longer exists. It should instead be preparing for a future that is very different from the past."[17] Nowhere is this truer than in trade policy, because it currently does not include the "likely impacts" of climate change.

"Likely impacts" and U.S. farm income in a historical trade related context

In 2016, the United States exported $38.1 billion in agricultural goods under NAFTA and imported $44.5 billion.[18] In 2016, total U.S. farm cash receipts for raw agricultural materials were about $358 billion.[19] Although agricultural goods include processed foods not included in U.S. farm cash receipts and although captive supply pricing in poultry and livestock makes cash receipts in those sectors difficult to calculate, NAFTA-related agricultural exports accounted for roughly one-tenth of U.S. farm cash receipts in 2016. However, an increase in agricultural exports often does not often result in an increase in farmer income, much less prosperity, even when government payments are added to cash receipts in the USDA's definition of net farm income.

Farmers sell their goods, often at below the cost of production, to the first link in the trade supply chain. For example, this month a farmer selling No. 2 yellow corn to Southern Minnesota grain

elevators would receive about $3.31 per bushel.[20] In 2017, the estimated cost of production in Southern Minnesota for a bushel of corn was $3.71.[21] Below cost of production farm gate prices facilitate U.S. agribusiness export dumping of row crops, as IATP has documented for most years since the 1996 "Freedom to Farm Act."[22] Tim Wise has analyzed U.S. policies that enable U.S. agricultural dumping and its impacts on Mexican producers.[23]

WTO disciplines on domestic subsidies to agricultural production (Aggregate Measures of Support) have failed to prevent agribusiness export dumping. A USMCA provision in the agriculture chapter to prevent dumping would, at the very least, begin a long overdue debate in trade policy. Instead, article 3.9 prohibits parties to USMCA from utilizing agricultural safeguard provisions authorized under the WTO.

In our 2016 letter to the USITC, we cited an Agricultural Policy Analysis Center (APAC) article demonstrating the agricultural trade deficit performance of Free Trade Agreements (FTAs) for cash-receipt based farm income since 1994. The Farm Bill's subsidy payments to compensate partially for below cost of production prices has not stemmed the erosion of farmer and rancher equity. As the 2017 Minneapolis Federal Reserve Bank agricultural survey noted, "Low commodity prices and relatively high fixed costs have compressed margins and created operating losses over several years for many producers. While strong yields and government program support have helped mitigate losses in many parts of the [9th FR] District, bankers have observed a significant reduction in producer working capital."[24] As a result, "74 percent of the bankers [surveyed] anticipate their median borrower to have a DSC [Debt Service Coverage] ratio below breakeven in 2017."

The Farm Bill, and not sales of raw commodities for diversion to international trade, remains the commodity-related source of farmer and rancher stability, however meager. As APAC noted last month, "One of the battle cries during the run-up to the adoption of the 1996 Farm Bill was, 'We'd

rather receive our income from the marketplace instead of the mailbox.' If all Congress does [in the now just passed Farm Bill] is 'enhance' the Agricultural Risk Coverage and Price Loss Coverage programs, the mailbox will have won out over the marketplace."[25] The mailbox is still a critical source of what the USDA counts as farm income, regardless of the hortatory claims made for trade-driven farmer prosperity.

A December summary by the Congressional Research Service of USDA Economic Research Service data states, "About 17% ($18,637) of [average] total farm household income [in 2018] is from farm production activities, and the remaining 83% ($92,684) is earned off the farm (including financial investments). The share of farm income derived from off-farm sources had increased steadily for decades but peaked at about 95% in 2000 (Figure 27).[26] Farm households without non-farm jobs, the main source of income for most farm households, go bankrupt. It is perhaps obvious to say that most farm households depend overwhelmingly, year-in and year-out, on non-farm income because of the misrepresentation that farm income (including government payments) depends on ever expanding exports. However, USDA argues:

> Our farmers' incomes are driven largely by the market prices they receive for the crops and livestock they sell. To support those prices and keep the farm sector viable, we need to expand demand for U.S. grown farm and food products—and that means expanding exports. With 95 percent of the world's consumers living outside the United States, global demand is on the rise and foreign sales are a key to the long-term health of our farm sector. Without export markets, U.S. agriculture would have larger domestic supplies, lower prices and reduced production, resulting in diminished rural economic activity.[27]

U.S. farmers of conventional crops and livestock have little to no control over the prices that they receive at elevators and stockyards, since those prices originate from either commodity exchange derivatives markets and/or in captive supply arrangements controlled by meatpackers. The United States can far more effectively and efficiently support U.S. farm gate prices, and U.S. farmers, by setting a loan rate price floor and by managing supply inventory.[28] Instead, overproducing

agricultural commodities for export in competition with other like-minded countries, has endangered the long-term economic, environmental and public health of the U.S. farm sector and rural communities. The main beneficiaries of U.S. agriculture and agricultural trade policy are the input and implement dealers of the "high fixed costs" and agribusiness processors and exporters who, according to IATP's analysis, are dumping row crops at export prices below the full cost of production. USDA presents the alternative to U.S. agricultural policy in support of farmers and rural communities as agriculture with no export markets. This is an unrealistic counterfactual scenario for evaluating the agricultural trade impacts under the USMCA.

Estimating the likely effects of "Trade in Products of Agricultural Biotechnology"

Nearly all of Chapter 3 on Agriculture, Section A, "Trade in Products of Agricultural Biotechnology," is copied from the Trans-Pacific Partnership Agreement (TPPA), Article 2.27.[29] The major, and likely very consequential, difference is this TPPA provision, deleted from the USMCA: "Nothing in this Article shall require a Party to adopt or modify its laws, regulations and policies for the control of products of modern biotechnology within its territory," (Article 2.27.3). USDA Secretary Sonny Perdue declared his agency will not regulate products of agricultural biotechnology,[30] save for a proviso that is meaningless in view of new genetic engineering techniques. Therefore, IATP assumes that the departure from the TPPA text is not intended to allow for, adopt, or change U.S. laws and regulations, but instead to increase pressure on Mexico to eliminate its ban on planting genetically engineered seeds, long sought by the biotechnology industry.

Indeed, a bill promoted by the industry, currently in the Mexican Senate, would criminalize (with up to eight years in prison) the planting of any seed detected to have patented gene sequences, however acquired.[31] On the other hand, if that legislation is not approved and the use of proprietary genetically modified seeds ensues, another impact would be yet more farmers leaving agriculture to

become migrants within Mexico or to the United States. Mexican officials say that they rely on U.S. regulator assurances to justify not labeling food products with genetically engineered ingredients, notwithstanding Mexican consumer right to know laws.[32]

It is difficult to determine economic benefits for U.S. exporters, based on the terms for agricultural biotechnology of the USMCA. The chapter's Article 3.1 definition for "agricultural goods" is based on Annex I to the WTO Agreement on Agriculture, which lists products corresponding to numbers in the Harmonized Item Description and Coding System (HS) maintained by the World Customs Union. The United States Harmonized Tariff Schedule recognizes numerous modifications of products (e.g. "modified whey") with specific HS numbers and item descriptions.[33] But since the HS (2018 Revision 14) does not distinguish between gene-edited and conventional agricultural products, such as corn,[34] attributing economic benefits to the non-regulation of those unregulated products will be, at best, estimates derived from industry acreage and yield sources diverted to export.

The non-recognition of genetic modification with a separate HS product number reflects the U.S. regulatory doctrine that no matter how much a genome (e.g. of corn) is altered in engineering, it "is not materially different in composition, safety and other relevant parameters from corn-derived food and feed currently on the market," to cite a U.S. Food and Drug Administration (FDA) letter of March 11, 2016 to Monsanto.[35] This letter, and thousands like it, repeats a 25-year-old doctrine of "substantial equivalence" between products of conventional plant breeding and those derived from genetic engineering to explain why, for example, the FDA will neither formally risk assess nor regulate MON 87419, modified to resist the herbicide Dicamba. (More than a million acres of U.S. crops not resistant to Dicamba have been damaged by the inherently volatile herbicide, which can drift miles from where it is sprayed.)[36] The substantial equivalence doctrine has long been criticized as unscientific, particularly regarding its failure to recognize the molecular differences

between GE plants and their conventional counterparts.[37] Nevertheless, this old doctrine underlies Section A provisions in the "modernized" New NAFTA.

Article 3.12 definitions for "product of agricultural biotechnology" and "product of modern biotechnology" likewise comprise all products in the HS. In theory, all "agricultural goods" could be a "product of modern biotechnology," but in practice there is no way to distinguish between sales of conventional agricultural goods and those of products derived from modern biotechnology.

Under the terms of the section on "Agricultural Trade in Products of Modern Biotechnology," the products do not have to be risk assessed or authorized by regulatory agencies to be traded, (Art. 3.14.2): "This Section does not require a Party to mandate an authorization for a product of agricultural biotechnology to be on the market." Logically, the patent owners of gene-edited fruits, vegetables, grains, oilseeds, animal agriculture and fish products, as well as sellers of the corresponding veterinary drugs, pesticides and fertilizer inputs, and the shippers of those products should benefit from the new rules to not regulate such products. Accordingly, the Biotechnology Innovation Organization welcomed the signing of the USMCA: "BIO supports the USMCA and appreciates the Administration's efforts to prioritize biotechnology innovation, including provisions that update intellectual property protections and agricultural market access to 21st century standards."[38]

BIO likewise has long advocated for the Low-Level Presence Occurrence (LLPO) provisions in the agricultural biotechnology section of the USMCA.[39] Their success in lobbying the U.S. Trade Representative to include their demands in the USMCA could, however, have unintended and negative consequences for U.S. agricultural trade. The LLPO provisions do not allow for the importing country to apply risk management measures resulting from the exporting country's regulatory failure to detect and prevent export of genetically engineered products unapproved in the importing country.

In practice, Section A enables exporting and importing entities (sometimes different regional subsidiaries of the same firm) to circumvent the risk management practices allowed under the WTO Agreement on Trade Related Sanitary and Phytosanitary Measures (SPS Agreement). For example, footnote 3 of Section A denies the importing country its WTO right to apply punitive measures, such as an import rejection or a fine on the importing or exporting entity, for including in a shipment a product unapproved in the importing country.

The Global LLP Initiative, of which BIO is founding member, was designed for genetically modified grains and oilseeds. However, Article 3.1 applies to all "agricultural goods" and products of agricultural biotechnology, including fruits, vegetables, live animals, animal agricultural products, fish, wheat, rice, oilseeds, feed grains, etc. There are no quantitative thresholds for any LLPOs under the USMCA, unlike existing thresholds for feed grains and oilseeds,[40] nor is there any requirement to agree on the frequency of what constitutes "on occasion" in the LLPO definition, (Article 3.12). Indeed, throughout this section, the legal burden is on the importing country to manage the LLPO at the port of entry by facilitating import, rather than on the exporting country's authority to explain how it failed to detect and prevent export of the genetically engineered agricultural product unapproved in the importing country.

Upon request from the importing country authority, "The exporting country shall (Article 3.15.2) "provide, on receiving permission of the [exporting] entity, if required" information the exporter is "likely to possess." It is a remarkable subordination of regulatory authority to commercial entities that importing country authorities may receive information to "manage" an LLPO only with the permission of the relevant entity in the exporting supply chain. What happens to the implementation of the LLPO provisions if the entity refuses permission, or if the information released

by the entity is inadequate for the importing country to "manage" the LLPO to the satisfaction of the exporting country and the entity chain it represents?

Among the information the "entity" may provide, if it so chooses, are the methods used to sample the shipment in which the LLPO occurs and the "validated technique" used to detect the LLPO. The purpose of Article 3.14.4 is to pre-empt the possibility that agricultural biotechnology products might not be approved in the importing country and "to reduce the likelihood of disruptions to trade in products of agricultural biotechnology." Notwithstanding all the Section A provisions that are targeted at reducing trade disruptions, the huge expansion in the agricultural goods to which Section A applies; the authority's dependence on entity permission for access to relevant LLPO information; the importing country's legal burden and administrative and technical costs of LLPO management to ensure import of unapproved and unlabeled GE products—these provisions are unlikely to enhance consumer confidence in the trade system. The importing governments may be forced to import unapproved agricultural biotechnology products and pay the costs of LLPO management, but consumers will not be forced to consume such products, as the USMCA becomes better known to the public.

Provisions and potential costs of the Chapter on Sanitary and Phytosanitary Measures (SPS)

According to IATP's analysis of USMCA Chapter 9, Sanitary and Phytosanitary Measures (SPS)[41], governments are required to be transparent about their SPS measures, but not about the industry-supplied information on which those measures are based. Transparency requirements to inform the public of the results of audits and other SPS information are qualified by exemptions for Confidential Business Information protected by domestic law. For example, "The auditing Party and audited Party shall each ensure that procedures are in place to prevent the disclosure of confidential information that is acquired during the audit process," (Article 9.11). Even the article that is explicitly

about transparency allows government to exempt from publication comments on SPS measures, even if the communication between governments and private parties concerns whether an SPS measure protects human, animal or plant health relevant to a traded food or agricultural product: "A Party shall also make available to another Party, on request, and to the extent permitted by the confidentiality and privacy requirements of the Party's law, significant written comments and relevant documentation considered to support the measure that were received during the comment period," (Article 9.13.10 (Transparency)). Transparency is required only of government authorities to explain their SPS measures and why they are not trade restrictive. Communication between government authorities and private entities commenting on a putatively trade restrictive measure may remain confidential.

The CBI culture in U.S. regulatory practice is re-enforced in the USMCA text. It took FDA until December 13 to name a commercial entity, Adam Farms, as one source of romaine lettuce contaminated by *E. Coli* O157:H7 in nearly eight-month long, multi-state outbreak of foodborne illness.[42] Some of the technical reasons for the time lag between initial identification of foodborne illness after consuming the contaminated lettuce are outlined below. In the event of cross-boundary shipment of a contaminated food, the audit by government officials of the facilities in the cross-border supply chain to trace back the origin of contaminated product cannot be aided by treating information about that audit as CBI.

The SPS chapter default is to minimize risk management measures, so as not to disrupt trade. For example, "Each Party shall consider not taking any measure as a risk management option where not taking any measure would achieve the Party's appropriate level of protection," (Chapter 9.6.10 (Science and Risk Analysis)). This is a novel way to demonstrate the claim of the USMCA text to be building on the WTO SPS Agreement (Article 9.3.1 b). We asked, using the example of an undisclosed

U.S. reduction in the audits of the Canadian meat exporting facilities[43], how would governments demonstrate that the "do nothing" measure would provide the WTO-required "appropriate level of protection," however governments publicly define that level, regarding meat consumption?

Whether or not an importing country's regulatory authority has adequate information to determine that an exported product complies with its SPS rules, the importing country must import: "For greater certainty, a Party is not stopping imports because it is undertaking a review if the Party stops imports on the basis that the review identifies that the information necessary to permit the importation of a good is lacking," (Footnote 1 to Article 9.6.15 (Science and Risk Analysis)). This footnote shows the role of science-based decision making in the USMCA: To validate the trade imperative even when scientific information is inadequate to enable risk analysis. Article 5.7 of the WTO SPS Agreement, which establishes the right of importing countries to provisionally adopt a SPS measure "where relevant scientific evidence is insufficient," is tossed into the dustbin of trade policy history—if this footnote prevails in a trade dispute. More broadly, the importing imperative acts against a precautionary approach in food and agricultural product regulation to protect consumer health.

Before we further analyze the SPS chapter text, however, it is crucial that USITC understand something of the institutional capacity of U.S. agencies to implement the agreement in a way that protects consumers, rather than defaulting to protecting agribusiness trade. The following illustration of U.S. agencies to detect, traceback and recall food products contaminated by pathogens by no means illustrates all the problems that U.S. agencies face in protecting animal, plant and human health, animal welfare and the environment (regarding invasive species). We do not intend to minimize, much less disparage, the bilateral initiatives of governments to improve SPS protections, such as the FDA's work with Mexico to improve produce safety for the increasing volume of produce

exports from Mexico to the United States.[44] But it is critical that the USITC convey to Members of Congress prone to interpret the agreement in terms of potential benefits for their district or state that there are human and financial costs to SPS policy failures that Members should understand as they interpret a complex text that they are forbidden to amend under the terms of the Trade Promotion Authority Act.

Understanding U.S. SPS institutional capacity and shortcomings: A few illustrations

In April 2016, IATP wrote to the USITC that assessing the likely impacts of the TPPA's SPS chapter was not only a matter of the terms of the TPPA, but also the regulatory capacity and resources of the governments to effectively implement the terms of the agreement. Effective and adequate resourced implementation and enforcement would provide the "appropriate level of protection" for agricultural plant, animal and consumer health, for animal welfare, and for the environment (particularly regarding invasive species). IATP reported that a General Accountability Office audit in 2015 found the Food and Drug Administration unable to inspect more than a third of export facilities required by the Food Safety Modernization Act provision to how such inspections could minimize the need for port of entry re-inspection of FDA-regulated food and food ingredient products.[45] The food industry, which advocated for the Voluntary Qualified Importer Program (VQIP) to expedite imports with reduced or no inspection intensity, was unwilling to supplement FDA's budget with user fee-based funds to implement the VQIP from TPPA countries and other trading partners.[46]

FSMA implementation has not improved greatly since IATP last wrote to USITC, according to a December 2016 Congressional Research Service report. Compliance dates for implementation of produce safety rules (January 27, 2019) and for Foreign Supplier Compliance Program (May 28, 2019)[47] may be delayed again as FDA faces the budgetary and regulatory challenges of other U.S. federal agencies. Following a decrease in FDA food safety resources in the FY 2018 budget,[48] the FY

2019 food safety budget may increase. However, what is important is not the simple quantity of the budget, but how it is used to respond to foodborne illness caused by contaminants in FDA-regulated foods.

In 2017, as of July, the Centers for Disease Control and Prevention (CDC) had investigated about 200 multi-state outbreaks of foodborne illness.[49] The CDC states, "When two or more people get the same illness and investigation shows it came from the same contaminated food or drink, the event is called a foodborne disease outbreak." Most of these outbreaks concerning FDA-regulated foods involve seafood or the contamination of horticulture products by pathogens of animal origin.

In 2017, the CDC published a study on foodborne illness outbreaks from 1996-2014 associated with imported foods.[50] The authors found that, "During 1996–2014, a total of 195 outbreak investigations implicated an imported food, resulting in 10,685 illnesses, 1,017 hospitalizations, and 19 deaths."[51] Imported food from Mexico was "implicated" in 42 outbreaks and food from Canada in 11 outbreaks. Not unexpectedly, as U.S. food import dependence increases, so do the number of foodborne illness outbreak originating with foreign foods.

U.S. implementation capacity and enforcement measures are critical for interpreting whether the SPS chapter of the USMCA enhances or impedes the ability of U.S. federal agencies, particularly the FDA and USDA, to prevent foodborne illness associated with imported foods or quickly traceback the origin of foodborne illness outbreaks to remove contaminated products from retail outlets and wholesalers. In December 2017, the Office of the Inspector General (OIG) of the Department of Health and Human Services reported on FDA's recall capacity and efficacy.[52] The OIG found that "FDA could not always ensure that firms initiated recalls promptly and that FDA did not always (1) evaluate health hazards in a timely manner, (2) issue audit check assignments at the appropriate level, (3) complete audit checks in accordance with its procedures, (4) collect timely and complete status reports from

firms that have issued recalls, (5) track key recall data in the RES, and (6) maintain accurate recall data in the RES [Recall Enterprise System]."[53] In response, FDA explained its product recall policies, procedures and the electronic database of the RES, and agreed to improve its procedures and RES.[54]

Nevertheless, FDA continues to experience lengthy traceback times for contaminated produce and as a result, product recalls are delayed. In June 2018, IATP summarized reporting on FDA's six-month effort to trace back the origin of a multi-state food borne illness outbreak caused by romaine lettuce contaminated with *E. coli STEC* O157.[55] In a May 31, blog FDA Commissioner Dr. Scott Gottlieb and Deputy Commissioner for Food and FDA official Dr. Stephen Ostroff explained how FDA conducted its traceback program, noting that chain of custody records were mostly on paper and sometimes incomplete. FDA advises, but does not require, the produce industry to keep electronic records.[56] IATP remarked that the Master Traceback Diagram,[57] which redacted the names of the produce firms as Confidential Business Information, would not likely enhance consumer confidence in FDA's traceback program, nor would the recommendation of nine consumer and food safety groups, in a May 24 letter to Dr. Gottlieb[58], to use blockchain computer technology to enhance the traceback process effectiveness if produce firms are allowed to maintain paper chain of custody records, and if FDA maintained the name of the produce firms with contaminated products as Confidential Business Information.

FDA is not alone in having lengthy traceback problems, further hindered by Confidential Business Information claims about public health information to protect trade and commerce. In November, IATP summarized reporting about USDA's year-long effort to trace back and recall contaminated turkey products.[59] While the contaminated turkeys were not imported, USDA's slow traceback and even slower product recall do not inspire consumer confidence, nor does USDA's delegation of its meat inspection authority to slaughterhouses and processing facilities, and rule to

allow increased production line speeds that reduce inspection time. As cited in IATP's summary, A Food and Water Watch press release cited Stan Painter, Chairman of the National Joint Council of Food Inspection Local Unions: "I have been an inspector for over 30 years and inspection has deteriorated because FSIS management has permitted it to do so."[60]

The costs of SPS food safety management failure is high, both in monetary terms and in terms of human suffering. As IATP wrote in our April 2016 letter to the USITC: "The Centers for Disease Control identified imported foods as the source of 18 of 120 foodborne illness outbreaks in 2015, but also estimated that only three percent of U.S. foodborne illness was reported to authorities, usually that which required hospitalization.[61]

Despite this massive underreporting of U.S. foodborne illness, health-related costs of acute foodborne illnesses in the U.S. have been estimated at $93.2 billion annually.[62] Expediting increased agricultural imports from TPP countries almost certainly will increase that cost, whether or not FDA requires U.S. food importers to strengthen their notoriously weak food traceability systems to identify the source of foodborne illness or food mislabeling.[63] Only about one-half of one percent of pathogen-caused foodborne illness can be traced back to a specific food,[64] due in part to the weakness of U.S. traceability.

Under the terms of the SPS chapter, a likely impact of agricultural trade, particularly in seafood and horticulture products, is that more contaminated, imported foods will be consumed in the United States, since the aforementioned 2017 CDC study has noted that more outbreaks of foodborne illness are increasingly associated with imported food generally. The likelihood of this outbreak origin outlook will be increased by the USMCA proposals to "streamline" bilateral negotiations to expedite the trade of food and agriculture products under SPS equivalence determinations that cover from single measures to whole SPS management systems.

These equivalence determinations are not only the result of a comparative review of rules, but include verifying audits of government SPS facilities, (e.g. port of entry sampling and testing facilities). The USMCA would expedite equivalence determinations by "streamlining" them. "Streamline" is one of the favorite euphemisms of the Trump administration's deconstruction of the administrative state:[65] "On request from the exporting Party, the importing Party´s competent authority shall consider whether a streamlined process may be used to determine equivalence." (Article 9.9.6) "Shall consider" is an oxymoronic blend of trade policy requirements and the "best endeavor" language that is acted upon only under the threat of dispute retaliation.

However, it is difficult to "streamline" an equivalence determination, unless that determination is based only on a comparative document review, without corroborating evidence in physical plant audits, both announced and unannounced. Article 9.10 (Audits), however, applies only to audits of government documentation and SPS facilities, not to audits of facilities in the export supply chain, which would determine to what extent governments effectively enforced and exporters complied with SPS rules.

Additional USMCA impacts on U.S. consumers

With most tariffs on consumer goods long since lifted in the original NAFTA, understanding the USMCA's impact on consumers means analyzing its non-tariff provisions. These encompass much of the agreement, making up a bureaucratic, complex and confusing web of rules. We have already discussed the negative impacts on consumers from the SPS and agricultural biotechnology provisions. In the section below, we address several other non-tariff provisions of the USCMA that will cause significant harm to consumers both in their pocketbooks, and by directly threatening their health and safety.

Major concerns include provisions that will make it more difficult to label consumer products; that promote or even require rushing consumer products to market without conducting sufficient safety testing; that allow corporations to prevent access to health and safety information on pesticides; that will keep medicine prices high and place roadblocks in the way of effective price negotiation in public healthcare programs including Medicare; and generally, that will burden government regulators with onerous procedures and obligations that will delay and impede the development, enactment and implementation of standards to protect the public in part by enabling industry to have an earlier and greater role in cross border intervention in the development and implementation of domestic policy. We address these concerns below:

Burdensome requirements in Chapter 28, Good Regulatory Practices, and the TBT Sectoral Annexes will delay and impede the development, enactment and implementation of public interest standards that protect consumers and the public.

The provisions of Chapter 28 apply broadly across all of government and affect virtually all regulations, even if not trade-related. For the first time, these procedural provisions would create obligations subject to dispute settlement among nations, enforceable through trade sanctions. The USMCA has many regulatory harmonization and equivalency provisions, additional cost-benefit and regulatory impact statement rules, and limits on what information may be used to support new regulations. Of particular concern are Article 28.13 and 28.14 which require procedures or mechanisms for retrospective review and opportunities for industry to seek to repeal regulations they dislike. Factors regulators "should consider" include "new opportunities to eliminate unnecessary regulatory burdens" and "ways to address unnecessary regulatory differences that may adversely affect trade," (Article 28.13.2). Regulatory authorities "shall provide" opportunity for interested persons to recommend modification or repeal, including when regulation "has become more burdensome than necessary to achieve its objective." Chapter 28 and the TBT Sectoral Annexes 12A-

12F also prioritize trade and commercial considerations over the public interest—inserting criteria such as "no more burdensome than necessary," and avoiding "unnecessary restrictions on competition in the marketplace" and "unnecessary regulatory differences." As we have detailed, the result will likely be delay, weakening and even repeal of consumer and other public protections.[66]

Multiple provisions seek to keep important health and safety information secret, with potentially serious consequences for public and worker health.

- ***Secrecy about agricultural chemicals.*** Article 20.45, "Protection of Undisclosed Test or Other Data for Agricultural Chemical Products," restricts access to information about pesticide safety. This provision allows countries to keep pesticide safety data secret and prevent other countries or third parties from seeing the evidence that their pesticides are safe or effective for 10 years. This would apply to the constantly revolving, patented new pesticides (like Roundup 2 that replaced Roundup) and effectively keep all safety data on these pesticides secret forever as new variants are introduced. This provision will affect the health and safety of farmworkers, backyard gardeners, and consumers of produce, and could also limit effective regulation of toxins in the environment.
- ***Restricting access to information about prepackaged foods and food additives***. Paragraph 3(a) of Annex 3-D, "Proprietary Formulas for Prepackaged Foods and Food Additives," limits requests for information relating to proprietary formulas for prepackaged foods or food additives "to what is necessary to achieve its legitimate objective." This provision inserts the restrictive "necessity test" into regulatory decisions about food labeling and regulation and could make it much more difficult for the Food and Drug Administration to compel companies to provide information on food additives. Paragraph 5 of this Annex, ostensibly a savings clause that preserves authority to list ingredients on food labels, disallows such labeling "when those standards would be an

ineffective or inappropriate means for the fulfilment of a legitimate objective." This language could limit labeling of prepackaged food by allowing challenges on the grounds of effectiveness and appropriateness, raising the bar on the FDA in justifying its regulations. These restrictions could have significant consequences because the FDA lacks safety information for hundreds of chemical additives already on the market and in our food. A study by the Natural Resources Defense Council identified 275 chemicals from 56 companies that appear to be marketed for use in food based on undisclosed safety determinations, and there may be hundreds more such secret additives.[67]

- ***Restricting access to information on chemical substances.*** Annex 12-A, Chemical Substances, states the parties "shall strengthen their cooperation" generally on chemical regulation and specifically, "they shall cooperate with a view to minimizing the differences in the use of safety data and safety data sheets." Paragraph 5(c) specifically identifies reducing differences in presenting information on material safety data sheets where information is "protected as confidential business information." The focus on CBI seems intended to keep more information hidden from workers and first responders, who rely on these hazard communication materials to protect themselves from both acute and long-term health impacts, and to assist in medical diagnoses.
- ***Rushing products to market without complete, or even minimal, safety information***. Provisions in the Sectoral Annexes to Chapter 12, Technical Barriers to Trade, require a "market first, regulate later" approach to the safety of consumer products. For example, Annex 12.B.5, Cosmetic Products, provides that marketing authorizations of cosmetic products are only allowed for health and safety concerns where "no less trade restrictive alternative is reasonably available," such as notifications and post-market surveillance. Yet at same time, this provision hampers the ability of

regulators to ensure that such notifications and post-market surveillance are effective, because they are not allowed to label products with a notification number. There are also limits on testing or retesting shade and fragrance variants, and language setting forth an evidence-free risk standard that "cosmetic products generally present a lower risk to human health or safety than medical devices or pharmaceutical products." Taken together, these provisions will handcuff regulators at a time when there is increasing recognition that these ubiquitous and mostly unregulated products can and do pose serious threats to human health (such as hair dye[68] and body spray fragrances[69]) as well as the environment (chemicals in sunscreens harming coral reefs[70] and ozone-depleting chemical accelerants[71]). Annex 12-E, Medical Devices, requires a similar approach. Regulators must "minimize likelihood of implementing requirements that could lead to substantial delays" in marketing products, (Article 12.E.5.2), and they "shall allow" a device to remain on market during periodic reauthorization unless there are "significant" safety, effectiveness or quality concerns, (Article 12.E.6.4).

- ***Increasing consumer healthcare costs.*** The USMCA will exacerbate the problem of high prescription drug prices through several of its provisions. Chapter 20, Intellectual Property Rights, Subsection C "Provisions Relating to Pharmaceutical Products," would establish new monopolies for already costly brand-name medicines in the intellectual property provisions. The agreement would require at least 10 years of marketing exclusivity for cutting-edge biologic medicines, such as many new cancer treatments, delaying the marketing of less expensive, biosimilar versions of these medicines. This would prevent the U.S. from fixing its current flawed system, locking in extreme monopoly protections that ensure high drug prices at the expense of patients' lives and at great cost to both family and government healthcare budgets.[72] In addition, Chapter 29, Publication and Administration, Section B: "Transparency and Procedural Fairness for

Pharmaceutical Products and Medical Devices" imposes new requirements on the Medicare program intended to make it more difficult to negotiate lower prices based on prices in other countries.

Conclusion

IATP hopes that these comments will assist the USITC in preparing its report to Congress on the likely impacts of the USMCA, including the interests of U.S. consumers. The USITC's task would be difficult even it was not under great time pressure to deliver its report to Congress. If the USMCA is approved by the Parties and implemented, we urge the USITC to continue to produce and publicize staff studies on the agreement's performance for the U.S. agricultural and rural economy and for agriculture and food-related public and environmental health. In particular, the USITC should address in future studies the capacity of trade policy to support, rather than undermine, U.S. and intergovernmental initiatives to adapt to climate change, and to reduce acceleration of the greenhouse gas emissions that are increasing the frequency and severity of both extreme weather events and longer term negative climate impacts.

Respectfully submitted,

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