Gene-Edited Crops and Food and the Bold Path Forward in U.S. Trade Agreements

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Note: This paper uses GM as acronym for genetically-modified but always spells out gene-edited or gene-editing rather than using GE because GE can stand for genetic engineering which can include both genetic modification and gene-editing.

I. Introduction

Genetically modified (GM) crops and food have been in existence in the global marketplace, or at least portions of it, for nearly 30 years[1] but not without significant controversy. The controversy over GM crops transpires both politically and diplomatically as illustrated by a formal World Trade Organization (WTO) dispute between two of the largest economies in the world– the United States and European Union.[2] Proponents of GM crops

1 *See Science and History of GMOs and Other Food Modification Processes*, U.S. FOOD & DRUG ADMIN, https://www.fda.gov/food/agricultural-biotechnology/science-and-history-gmos-and-other-food-modification-processes (last updated Apr. 19, 2023) [https://perma.cc/T3NB-XF8H] (noting that the first GMO produce became available for sale in 1994).

2 *See* EUR. UNION CTR. OF N.C., THE EU-US DISPUTE OVER GMOS: RISK PERCEPTIONS AND THE QUEST FOR REGULATORY DOMINANCE 1 (2007).

point to increased yields and streamlined crop management that increase food security and help take care of the nutritional needs of a growing world populations, while opponents worry about allergic reactions, herbicide-resistant weeds, and ethical concerns. Twenty-six countries produce GM crops, although five countries (United States, Brazil, Argentina, Canada, India) cultivate the vast bulk of these crops.[3] However, in the past several years, new plant breeding technologies (NPBTs) relying on new biotechnology have been developed by agricultural scientists and businesses–termed gene editing.[4] Gene-edited crops differ from GM crops in that they typically only involve silencing (or knocking-out or deleting) a gene or changing the sequence of the endogenous genes in a plant, rather than inserting exogenous (or foreign) DNA.[5] Further, gene-edited crops and food will likely involve many more companies and countries.

However, if gene-edited crops and resulting food are to avoid succumbing to the harsh regulatory conditions, political controversy, and negative consumer misperceptions in many major export markets that have befallen GM crops and food, rapid action must be taken by the United States and other gene-editing-allied countries to widen the base of support to prevent unscientific and unnecessarily burdensome regulation and trade barriers to such crops and food. Specifically, because litigation under current trade agreements including the WTO will be ineffective, the United States must pursue bolder pro-gene editing provisions, including provisions for approval standards and labeling, in international trade agreement negotiations. In the short term, non-comprehensive regional agreements or bilateral issue-specific agreements can be utilized to create momentum for provisions in future comprehensive free trade agreements and a WTO plurilateral agreement.

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3 *See* Mayra Teresa Garcia Ruiz et al., *Profile of Genetically Modified Plants Authorized in Mexico*, 9 GM CROPS & FOOD 152, 154 (2018).

4 *See Genome Editing in Agricultural Biotechnology*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/agricultural-biotechnology/genome-editing-agricultural-biotechnology (last updated May 9, 2023) [https://perma.cc/Z2GE-XFCB].

5 *See* Hermione Dace, *Gene-Editing in Food Production: Charting a Way Forward*, TONY BLAIR INST. FOR GLOBAL CHANGE (Mar. 17, 2021), https://www.institute.global/insights/tech-and-digitalisation/gene-editing-food-production-charting-way-forward [https://perma.cc/H2BM-CWCX] ("Unlike genetic-modification techniques, gene editing does not involve the insertion of foreign genetic material from other species. Gene editing essentially allows us to edit genes in a way that happens anyway in nature, but much faster.").

Current trade agreements do not provide a certain pathway to ensure the trade of gene-edited products. WTO litigation against negative treatment of gene-edited crops and food will be ineffective due to the collapse of the WTO Appellate Body and the resulting inability to receive binding rulings because losing defendant countries can appeal "into the void," thus preventing automatic adoption by the WTO's dispute settlement body of rulings.[6] Additionally, prior GM crop litigation in the WTO, as well as cases dealing with hormone-treated beef, suggests countries may be unwilling to change regulations in these areas in response to losing a WTO case–and indeed such a case may harden consumer (mis)perceptions.[7] Thus, primarily regional and bilateral negotiations rather than dispute settlement within the WTO must be relied upon.

One of the best forums to pursue negotiations of pro-gene-edited crop and food provisions would be in traditional, comprehensive free trade agreements (FTAs) that include market-access/tariff-cutting commitments for the maximum amount of leverage for the United States in negotiations. However, the United States has essentially abandoned traditional free trade agreement negotiations and has not concluded a free trade agreement with a new partner country since 2012.[8] It is likely the United States will return to negotiate traditional, comprehensive FTAs as other countries continue to conclude such deals creating negative tariff margins for U.S. products in other markets, but it could be a number of years before this occurs. A WTO agreement could spread pro-gene-editing disciplines to potentially 164 member countries in that organization but is unlikely to be successful due to the fractured negotiating pillar within the WTO and difficulties achieving

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6 *See* Simon Lester, *Ending the WTO Dispute Settlement Crisis: Where to from Here?*, INT'L INST. FOR SUSTAINABLE (Mar. 2, 2022), https://www.iisd.org/articles/united-states-must-propose-solutions-end-wto-dispute-settlement-crisis [https://perma.cc/XAA3-QFLW] (describing how the US blocking appointments to the WTO Appellate Body is making it more difficult to enforce WTO obligations).

7 *See* RENEE JOHNSON, CONG. RSCH. SERV., R40449, THE US-EU BEEF HORMONES DISPUTE 2 (2015).

8 *See* Matthew Schaefer, *Can Geopolitics Help Restore Missing Tools to the US Tool Tradebox?*, YEUTTER INST. FOR INT'L TRADE: BLOG, (Aug. 22, 2022), https://yeutter-institute.unl.edu/can-geopolitics-help-restore-missing-tools-us-trade-toolbox [https://perma.cc/U7KQ-ACV3].

consensus amongst such a large membership.[9] Even a plurilateral agreement in the WTO may be a bridge too far in the current WTO negotiating environment. However, progress can be made in the current new-styled trade negotiations the United States is engaging in. Unlike traditional U.S. free trade agreements negotiated in the past three-decades, these new-styled negotiations are non-comprehensive and do not include traditional market-access, tariff-cutting discussions. Nonetheless, they still do address technical and regulatory barriers to agricultural trade. These new-styled negotiations are occurring in two broad regional forums, the Indo-Pacific Economic Framework (IPEF)[10] and the Americas Partnership for Economic Prosperity (APEP),[11] and with some individual countries, such as Kenya and Taiwan.[12]

While the United States does not have tariff cuts to use as leverage in these negotiations,[13] it can likely successfully appeal to other countries' desire for agriculture sustainability and climate concerns as a reason to advance trade in gene-edited crops and

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9 *Id.*

10 *See Indo-Pacific Economic Framework for Prosperity*, OFF. OF THE U.S. TRADE REPRESENTATIVE, https://ustr.gov/trade-agreements/agreements-under-negotiation/indo-pacific-economic-framework-prosperity-ipef (last visited Sept. 18, 2023) [https://perma.cc/V4VP-UYEP].

11 *See Fact Sheet: President Biden Announces the Americas Partnership for Economic Prosperity*, WHITE HOUSE (June 8, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/08/fact-sheet-president-biden-announces-the-americas-partnership-for-economic-prosperity/ [https://perma.cc/V4VP-UYEP].

12 *See USTR Releases Summaries From U.S.-Taiwan 21st Century Trade Initiative Negotiations*, OFF. OF THE U.S. TRADE REPRESENTATIVE (Mar. 16, 2023), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2023/march/ustr-releases-summaries-us-taiwan-21st-century-trade-initiative-negotiations [https://perma.cc/GP82-RQRF]; *USTR Releases Summaries from U.S.-Kenya Strategic Trade and Investment Partnership Negotiations*, OFF. OF THE U.S. TRADE REPRESENTATIVE (May 23, 2023), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2023/may/ustr-releases-summaries-us-kenya-strategic-trade-and-investment-partnership-negotiations [https://perma.cc/E3GN-BCUK].

13 It would help negotiations if tariff-cuts and traditional market access were also on the table, but thus far the Biden Administration has chosen not to place tariff-cuts on the table, *see, e.g.*, William Allan Reinsch & Elizabeth Duncan, *Are Market Access Negotiations in the IPEF Unnecessary?*, CTR. FOR STRATEGIC & INT'L STUDS.: CRITICAL QUESTIONS (June 24, 2022), https://www.csis.org/analysis/are-market-access-negotiations-ipef-unnecessary [https://perma.cc/2J3T-DZGN].

food.[14] In addition, the United States should also engage in issue specific trade negotiations on agriculture biotechnology with other key countries not otherwise involved in IPEF, APEP, or current bilateral negotiations that are already considering GM regulatory reform and/or that are favorably inclined to gene-edited crops and food. Recent conclusion of issue-specific agreements by the United States, such as the critical minerals deal with Japan,[15] show such negotiations can succeed. Such a strategy can establish pro-gene-editing regulatory entryways via one or more large market economies in Europe, Africa and Asia, and lock in already largely favorable regulatory regimes within the Americas. Once multiple entryways have been established in each continent, a plurilateral agreement within the WTO might be possible with greater leverage and momentum. Agreements reached should be bold and include provisions not just on transparency and reinforcement of science-based regulation obligations in existing agreements, but also include provisions on the *approval* of gene-edited crops and food that go beyond recent provisions in the United States-Mexico-Canada (USMCA) to include a measure of mutual recognition and/or harmonization as well as provisions regarding their *labeling*.[16] The timing and nature of such agreements, of course, should be carefully considered. If a binding agreement with the United States may lead to resistance to a pro-gene-editing reform effort already underway, then an agreement can be delayed and serve to lock in reforms once made or a political commitment (non-legally binding agreement) might be utilized. However, in some cases, agreements can be used

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14 Indeed, those reasons are among the reasons the EU Commission cited in support of its proposal to relax rules on gene-edited crops and goods in July 2023. *See, e.g.*, *Frequently Asked Questions: Proposal on New Genomic Techniques*, EUR. COMM'N (July 5, 2023), https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_3568 [https://perma.cc/ZW2Q-JFEN].

15 *See United States and Japan Sign Critical Minerals Agreement*, OFF. OF THE U.S. TRADE REPRESENTATIVE (Mar. 28, 2023), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2023/march/united-states-and-japan-sign-critical-minerals-agreement [https://perma.cc/76UQ-K5EF]. It is true that tax incentives within the Inflation Reduction Act of 2022 created strong incentives for Japan and others to conclude such agreements. Issue specific gene-editing agreements would have to rely on other incentives, such as agriculture sustainability, decreased pesticide use, or climate.

16 This article will not address unfair trade practices related to gene-editing technology—such as mandatory licensing provisions, lack of patentability, and failure to protect trade secrets—although those are very real and present concerns for gene-editing developers and providers.

to spur a fulsome reform, rather than an effort that only has the legs to go part way.

While establishing pro-gene-editing provisions in regional and bilateral new-styled or issue-specific agreements, the U.S. government should not relax its effort to establish fair treatment of GM crops and food as well. In addition to being a leading country in GM crop production, it will likely be true that some gene-editing techniques (now or in the future) may fall within more stringent GM crop and food regulations. Thus, the United States and other gene-editing-supportive countries must continue to pursue support for transparent, scientifically justified regulation of GM crops and food as well.

Part II of this article defines gene editing, distinguishes gene-edited crops and food from GM counterparts, and explores the benefits and concerns with gene-edited crops and food. Part III examines the international legal landscape for gene-edited crops and food, in particular their treatment under the WTO Sanitary and Phytosanitary (SPS) Agreement, the Cartagena Protocol to the Convention on Biological Diversity, and in enhanced U.S. free trade agreement (FTA) provisions and non-comprehensive trade agreement provisions that seek to encourage trade in gene-edited crops and food, specifically provisions within the US-Mexico-Canada Agreement (USMCA), and the U.S.-China Phase I trade deal. Part IV provides an overview of domestic GM and gene-edited crop and food regulation across the globe and explores the challenges and pitfalls of the current patchwork of national regulatory regimes for gene-edited crops and food. Part V proposes a path to ensuring favorable treatment of gene-edited crops and food, specifically in the short-term, using current negotiations on broad regional and bilateral non-comprehensive trade agreements as well as pursuing issue specific agreements in major entryway markets in all major regions of the world. It also recommends pro-gene-editing provisions, including bolder ones than in existing agreements, for inclusion in these trade agreements. Part VI analyzes the important issue of labeling of GM and gene-edited food, including an analysis of international labeling standards and international trade agreement constraints on national labeling regimes. This discussion includes review of the WTO TBT agreement and USMCA labeling obligations. Part VII concludes.

II. Defining and Distinguishing Gene-Edits Crops and Foods and Exploring the Benefits of and Concerns Over these Novel Crops and Foods

This part begins by exploring the benefits of genetically modified (GM) and gene-edited crops and food. It then distinguishes gene-edited crops and food from GM counterparts with the most basic distinction being that gene-editing processes generally do not have foreign DNA remain in the resulting product. Concerns over gene-edited crops and food are then discussed. In sum, the benefits of gene-edited crops and food far outweigh their downsides.

A. Benefits of GM & Gene-Edited Crops

The direct benefits of GM and gene-edited crops are at least two-fold: increased yields and simplified crop management.[17] And, of course, both of these benefits have a number of follow-on advantages. Higher yields and streamlined crop management can improve food security generally[18] and also potentially take care of a growing world population's caloric and nutritional needs more readily.[19] The FAO estimates there will need to be 70% more food grown by 2050.[20] Compared to the conventionally bred analogues, GM crops can enhance nutritional value of foods.[21] For example, golden rice—a GM variety—contains much more vitamin A reducing blindness caused by deficiency of the vitamin.[22]

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17 *See* Mauro Vigani & Alessandro Olper, *Patterns and Determinants of GMO Regulations: An Overview of Recent Evidence,* 18 AGBIOFORUM 44, 50 (2015); Matin Qaim, *Role of New Plant Breeding Technologies in Food Security and Sustainable Agricultural Development*, 42 APPLIED ECON. PERSPS. & POL'Y 129, 130, 133 (2020) ("[New plant breeding technologies] could contribute to higher crop yields, lower use of chemical fertilizers and pesticides, better crop resilience to climate stress, reduced postharvest losses, and more nutritious foods . . .").

18 Vigani & Olper, *supra* note 17, at 50; *see also* Qaim, *supra* note 17, at 133.

19 *See* Qaim, *supra* note 17, at 129 ("More than 800 million people worldwide are chronically hungry, and 2 billion are micronutrient-deficient.").

20 *World Must Sustainably Produce 70 Per Cent More Food by Mid-Century – UN Report*, UNITED NATIONS: UN NEWS (Dec. 3, 2013), https://news.un.org/en/story/2013/12/456912 [https://perma.cc/GJR4-N4S5].

21 *See* Kathleen L. Hefferon, *Nutritionally Enhanced Food Crops; Progress and Perspectives*, 16 INT'L J. MOLECULAR SCI. 3895, 3895–96 (2015) (describing how GM food crops can enhance the nutritional value of single-crop diets).

22 Guangwen Tang et al., *Golden Rice Is an Effective Source of Vitamin A*, 89 AM. J. CLIN. NUTRITION, 1776, 1776 (2009).

Environmental benefits in terms of lower pesticide needs has also been highlighted, including with Bt crops now even grown on the African continent in Kenya.[23] Other environmental benefits include potential benefits to the environment such as lower green-house gas emissions through less fuel for tilling, for example.[24] Less land use pressure on natural habitats and less soil erosion/improved soil quality are also potential benefits.[25]

GM and gene-edited crops allow high yields and thus reduce the need for additional crop land without the associated need for increased fertilizers and pesticides and increased water and fuel usage.[26] The vast bulk of GM products are produced by five countries and are of the same general plant type, namely herbicide and insect resistance, and in four primary crops, namely soy, corn, cotton, and oilseed rape. This has been true for most of the past two decades.[27] Gene-editing techniques are likely to involve a much wider and diverse set of crops.

B. Gene-Edited Crops: Defined and Distinguished from GM Crops

Traditional GM crops involve transgenics—the movement of a

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23 *See* Patrica Nanteza, *Bt Cotton Gives Kenyan Farmers a Reason to Smile Again*, ALL. FOR SCI. (Mar. 24, 2022), https://allianceforscience.org/blog/2022/03/bt-cotton-gives-kenyan-farmers-a-reason-to-smile-again/ [https://perma.cc/K26B-ZSBJ].

24 *See* Vigani & Olper, *supra* note 17, at 50; *see also* Sommer Brokow, *Scientist Calls for Renewed Debate on Plant Breeding Technologies*, UNITED PRESS INT'L (Apr. 27, 2020), https://www.upi.com/Science_News/2020/04/27/Scientist-calls-for-renewed-debate-on-plant-breeding-technologies/6971588004234/ [https://perma.cc/4DSN-PW2M] ("Martin Qaim, German Researcher, states new breeding technologies 'invented a few years ago' are able to 'make better use of soil nutrients' so that they don't need as much fertilizer, he said. And the new technologies can also help crops develop new traits faster to adapt to climate change," (quoting Quaim, *supra* note 17, at 130)).

25 *See* Vigani & Olper, *supra* note 17, at 50 (the so-called Green Revolution had led to the following: " . . . farmers' use of irrigation water, chemical fertilizers and pesticides strong increased. The overuse of these inputs in some regions has led to falling groundwater tables, soil and water pollution, nitrous oxide emissions, and environmental issues.") *See also* Huang, Weigel, Beachy, & Li, *A Proposed Regulatory Framework for Genome-Edited Crops*, 48 NATURE GENETICS 109, 110 (2016).

26 *See* Dace, *supra* note 5 (noting that GM crops "need to use fewer resources like land, water, and fertilisers to produce the same or increased yield").

27 *See* Eva Gelinsky & Angelika Hilbeck, Commentary, *European Court of Justice Ruling Regarding New Genetic Engineering Methods Scientifically Justified: A Commentary on the Biased Reporting About the Recent Ruling*, 30 ENV'T SCIS. EUR. 1, 5 (2018).

gene from one species to another. In contrast, gene-edited crops involve removal of a gene or copying a sequence from a highly related species.[28] Gene editing often results in an end product with no "foreign" or "exogenous" DNA and often results in a product that could occur through conventional breeding technologies—mutagenesis—but gene editing achieves the results much quicker and much more efficiently.[29] The science editor of the Guardian, Ian Sample, analogizes gene editing to using the find-and-replace feature to correct words in a digital word processor: "With gene editing, researchers can disable target genes, correct harmful mutations, and change the activity of specific genes in plants and animals[.]"[30]

The lack of foreign DNA in gene-edited crops should theoretically reduce concerns with gene-edited products compared to GM. Genome editing is in many ways even more precise and predictable than transgenesis: "It is by nature similar to the use of spontaneous variants or induced mutations in conventional breeding, with the advantage that only the desired change is introduced."[31] While transgenes—or foreign or exogenous genes—are sometimes used as delivery mechanisms in gene editing, they can be removed such that no transgenes remain in the final product.[32] Any unwanted transgenes can be removed through either self-crossing or backcrossing methods, and those same methods can be used to eliminate any "off target"[33] mutations that were not part

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28 *See* Dace, *supra* note 5; Abby Meyer & Sara Dastgheib-Vinarov, *The Future of Food? CRISPR-Edited Agriculture*, FOOD & DRUG LAW INST.: UPDATE MAGAZINE (Winter 2021), https://www.fdli.org/2021/11/the-future-of-food-crispr-edited-agriculture/ [https://perma.cc/UYD9-FFRJ].

29 *See* Dace, *supra* note 5, at para. 10; *see also* Meyer & Dasgheib-Vinarov, *supra* note 28, at para. 7, 21.

30 Ian Sample, *What is Gene-Editing and How Can it be Used to Rewrite the Code of Life*, GUARDIAN (Jan. 15, 2018), https://www.theguardian.com/science/2018/jan/15/gene-editing-and-what-it-really-means-to-rewrite-the-code-of-life [https://perma.cc/A6KH-ZRP7].

31 Huang et al., *supra* note 25.

32 *Id.* at 109 (describing different mechanisms).

33 *See* Mark H. J. Sturme et al., *Occurrence and Nature of Off-Target Modifications by CRISPR-Cas Genome Editing in Plants*, ACS AGRIC. SCI. TECH. 192, 193, 199 (2022) (noting that "off-target modifications, which are usually defined as changes to the DNA or RNA, in regions other than the target site, are known to occur as a consequence of gene editing" and that off-target mutations occurred less frequently than spontaneous mutations

of the design.[34]

Thus, we have three possibilities for breeding in essence: conventional breeding, genetic modification, and most recently, gene editing. Gene editing is just the latest tool for manipulating crop genomes for the benefit of human nutrition and environmental sustainability. The manipulation of crop genomes by humans has occurred for thousands of years, with most of it occurring in a "random and non-targeted manner" and utilizing "simple trial-and-error approaches."[35] Gene editing accelerates this process.[36]

Gene-edited crops and food are on the rise. The first gene-edited crop to be formally declared as exempt from USDA regulation was white mushrooms in 2016,[37] thirty-three years after the first GM plant (tobacco receiving an anti-biotic resistant gene) was produced.[38] One gene-edited product already being served to

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and that "we observed from literature that the chance of an off-target mutation occurring in the genome is low").

34 *See* Gerhart U. Ryffel, *Transgene Flow: Facts, Speculation and Possible Countermeasures*, 5 GM CROPS & FOOD 249, 258 (2014).

35 Huang et al., *supra* note 25, at 110 ("Modern conventional plant breeding, draw¬ing on the insights of Darwin and Mendel, has made enormous contributions to increased global food production. It encompasses a broad range of techniques that go beyond the simple cross fertilization of existing cultivars, involv¬ing, for example, wide crosses between related species, in vitro fertilization, induction of poly¬ploidy, protoplast fusion and mutagenesis with chemicals or radiation. Sensibly, Sensibly, the products of sexual crosses, mutagenesis and tissue culture–based plant breeding are free of government regulation other than registration of varieties. However, conventional breeding is limited by the ability to introduce novel traits not present in the domesticated or wild germplasm; this restriction has been overcome by genetic modification (GM) techniques using transgenes introduced by several different methods. GM methods were initially used to insert DNA sequences from other species, such as selected genes for anti-insect proteins from Bacillus thuringiensis, which were previously in wide use as externally applied pesticides. . . . Similarly, often poorly justified criticism has been leveled against so-called 'cisgenesis', in which genes from the same or a closely related species are introduced by DNA transformation, even though the European Food Safety Authority (EFSA) has concluded that 'similar hazards can be associated with cisgenic and conventionally bred plants'").

36 *See id.*

37 *See* James Vincent, *Gene-Edited Mushroom Doesn't Need USDA Approval for You to Eat It*, VERGE (April 18, 2016), https://www.theverge.com/2016/4/18/11449700/gened-edited-mushrooms-crispr-usda-approved [https://perma.cc/RL5X-AR5V].

38 *See* A. S. Bawa & K. R. Anilakuwar, *Genetically-Modified Foods: Safety, Risks and Public Concerns*, 50 J FOOD SCI. TECH. 1035, 1046 (2013) ("The first genetically-modified plant was produced in 1983, using an anti-biotic resistant tobacco plant[.]").

restaurant customers is a more stable form of soybean oil that avoids the need for added and dangerous trans fats made by Catlyx[39] and a more waxy corn that will be beneficial as a thickener and stabilizer for numerous food products made by Corteva Agriscience, the agriculture division of DowDuPont.[40] But many additional ideas for gene-edited crops and produce are in development—lettuce that can be grown in dry conditions, wheat that is gluten-reduced, and strawberries that might be picked by machine.[41] Despite these innovations, there are concerns that gene-edited foods could run into the same politically charged trade and production regulatory barriers that have impacted GM foods and crops. In some countries, gene-edited food and crops are subject to the same regulation as GM food and crops[42]—regulations that have been implemented in a highly restrictive manner.

Also in contrast to GM crops and foods, which are largely dominated by a few countries and a few companies, one early study on liberal gene-editing regulation in Argentina "suggests that gene editing could drive further innovation and 'democratization' of agricultural biotechnology, thus leading to increased productivity and economic development, if managed under effective regulatory processes."[43] The greater ability of U.S. small and medium-sized companies, along with universities, to benefit from favorable gene-edited crop and food regulation has been further supported by Executive Orders issued during the Trump and Biden Administrations.[44] The Trump Administration Executive Order

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39 *See* Megan Molteni, *The First Gene-Edited Food Is Now Being Served*, WIRED (Mar. 20, 2019), https://www.wired.com/story/the-first-gene-edited-food-is-now-being-served/ [https://perma.cc/UX9G-DX7R].

40 *See* Karen Weintraub, *Crispr Gene-Editing Will Change the Way Americans Eat — Here's What's Coming*, GUARDIAN (May 30, 2019), https://www.theguardian.com/us-news/2019/may/30/crispr-gene-edited-food-technology-us-produce [https://perma.cc/PC34-8H7M].

41 *See id.*

42 See *infra* notes 189-204 and accompanying text (discussing EU regulation).

43 *See* Agustina I. Whelan et al., *Gene-Editing Regulation and Innovation Economics*, 8 FRONTIERS BIOENG'G & BIOTECH. 1, 7 (2020).

44 *See* U.S. Dep't of Agric., U.S. Food & Drug Admin. & U.S. Env't Protection Agency, *Modernizing the Regulatory System for Biotechnology Products*, UNIFIED WEBSITE FOR BIOTECH. REGUL., https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home/modernizing/modernizing_biotechnology_framework (last visited Sept. 29, 2023)

directed each regulatory agency to review its regulations every 90 days for a period of two years "to remove undue barriers that impede small, private United States developers, the United States Government, and academic institutions from bringing innovative and safe genome-edited-specialty-crop-plant products to the marketplace."[45] The Biden Administration Executive Order demanded additional clarity from various agencies, which should be of particular benefit to small and medium-sized companies.[46] With that said, large traditional GM developers will also benefit from favorable regulation of gene-editing technology. Indeed, for the largest agricultural companies—Corteva, Syngenta, BASF, and Bayer (the latter of which has recently acquired Monsanto)—the "long game is to use CRISPR to develop better versions of their serious moneymakers, the 'elite' varieties of a wide range of crops that have big commercial markets."[47] These large multinationals "sell dozens of kinds of elite corn seeds—for example, inbred strains that consistently have high yields or reliable resistance to herbicides" but "[c]reating the genetic purity needed for an elite variety typically takes traditional breeding of many generations of plants, and CRISPR is seen as the cleanest way to improve them quickly."[48]

C. Concerns Regarding Gene-Edited Crops & Foods

Despite the differences between the two types of products, it is

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[https://perma.cc/8XPW-2S6H] ("In 2019, Executive Order (EO) 13874 recognized that advances in biotechnology have the potential to revolutionize agriculture, enhance rural prosperity, and improve the quality of American lives. . . EO 13874 ordered additional steps be taken to further modernize the regulatory framework . . . In 2022, President Biden issued Executive Order (EO) 14081, Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy. EO 14081 aims to enable innovative solutions for challenges in health, climate change, energy, food security, and agriculture; solutions that will improve supply chain resilience and national and economic security. To further facilitate development and commercialization of safe biotechnology products in the United States, EO 14081 ordered renewed efforts to improve the clarity and efficiency of regulatory processes for biotechnology products and increase coordination and communication between federal regulatory agencies.").

45 Exec. Order No. 13,874, 84 Fed. Reg. 27,899 (June 14, 2019).

46 Exec. Order No. 14,081, 88 Fed. Reg. 25,711 (Apr. 27, 2023).

47 *See* Jon Cohen, *To Feed Its 1.4 Billion, China Bets Big on Genome Editing of Crops*, SCIENCE (July 29, 2019), https://www.science.org/content/article/feed-its-14-billion-china-bets-big-genome-editing-crops [https://perma.cc/A2RU-RNXV].

48 *See id.*

not altogether clear that the reaction to gene-edited crops and foods will be different than that to GM crops and foods. A number of possible health concerns have been raised by critics of gene-edited crops and foods, including the concern that gene-edited plants could potentially be toxic or allergenic if modified proteins are accidentally produced in the plant.[49] One example given is if a potato's "green gene" is accidentally turned off, then the warning sign for when a potato is releasing toxins would no longer be active.[50] Environmental concerns have also been raised, such as worries that the increased fitness and survivability of gene-edited crops could impact other plants and landscapes.[51] For example, herbicide-resistant soybeans are blamed by some for herbicide-resistant weeds that cause crop losses.[52] While most or all of these concerns can be addressed or are not greater with respect to gene-edited crops than those achieved through conventional breeding, others have raised ethical concerns that could block gene-edited crop and food approvals: "When it comes to the techniques involved with gene editing a crop or other food for a desired trait, integrity is compromised at several levels and none has anything to do with crossing species lines. The integrity lens makes it clear the ethics is not resolved by debating naturalness or species boundaries."[53]

However, these concerns pale in comparison to the benefits. Yet, politics and consumer (mis)perception will play a role in some countries' regulatory responses to gene-edited products as is true with GM products. If developed countries squash gene-edited crops and food, many developing countries that could benefit immensely from increased productivity will be harmed.

III. The International Legal Landscape

Gene-edited crop and food regulation is a trade issue because

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49 *See* Gelinsky & Hilbeck, *supra* note 27, at 4.

50 *See* Weintraub, *supra* note 40, at para. 18 ("[I]f the green gene were accidentally turned off, potatoes could release toxins without the warning.").

51 *See* Gelinsky & Hilbeck, *supra* note 27, at 4.

52 *See id.* (describing the development of herbicide-resistant weeds and noting that "[s]ome scientists are concerned that genes from GMO crops may spread to conventional crops or related species, in a process known as outcrossing").

53 *See* Christopher J. Preston & Trine Antonsen, *Ethicists: We Need More Flexible Tools for Evaluating Gene-Edited Food*, CONVERSATION (May 26, 2020), https://theconversation.com/ethicists-we-need-more-flexible-tools-for-evaluating-gene-edited-food-129531 [https://perma.cc/6RXP-6WJC].

the technology, the seeds, the crops, and the food products of gene-edited technology are all tradeable goods—and in fact their benefits are minimized if they cannot be traded. The two major multilateral agreements impacting the regulation and trade of gene-edited crops and food are the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Agreement and the Cartagena Protocol. The possibility of conflict between these agreements is small but present. Bolder, more detailed, pro-gene-editing provisions in future U.S. trade agreements will show such conflicts, if present, are small in nature, display that Cartagena Protocol has flexibilities allowing pro-gene-editing regulation, and eliminate any haze of uncertainty created by the Cartagena Protocol's definitional ambiguities. Further, as later-in-time and more specific rules, such provisions in future trade agreements will create the operative rules opening up trade in gene-edited crops and food as both a legal and practical matter. Indeed, more recently, the United States has sought to promote trade in gene-edited crops and food within the USMCA and the China Phase I trade deal. While these recent agreements are a good first step, bolder provisions should be sought in future agreements with key entryway countries in various regions of the world.

A. World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Agreement

The WTO Sanitary and Phytosanitary Agreement ("SPS Agreement")[54] is the most relevant agreement to regulation of gene-edited foods. The SPS agreement defines an SPS measure as any measure applied:

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

54 Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1995, Marrakesh Agreement Establishing the World Trade Organization Annex 1A, 1867 U.N.T.S 493 [hereinafter SPS Agreement].

> Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
>
> (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.
>
> Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.[55]

Applying this language, a WTO panel has found that the E.U.'s moratorium on GM products fell within the definition of an SPS measure under the agreement. Specifically, the concern that a GM product would cause an "allergic or toxic reaction on the part of consumers" and the concern that GM products could lead to the development of antibiotic-resistant bacteria fell under sub-paragraph (b), and the concern that GM products could lead to the spread of herbicide-resistant weeds fell within sub-paragraph (d) of the definition.[56]

Similarly, a country could argue that gene editing, in certain circumstances, is being regulated due to concerns over allergies, toxic reactions, anti-biotic resistant strains of bacteria and concerns of cross-contamination (or transfer) to non-target organisms. Thus, the SPS definition will cover those types of regulations as well.

However, the SPS Agreement requires measures to have a valid basis. While there is a presumption of compliance with the agreement to any SPS measure that "conforms" to an international standard[57] and the Agreement allows countries to choose their own level of protection, government measures must have a scientific

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55 *Id.* annex A, para. 1(a)–(d).

56 WTO Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WTO Doc. WT/DS291/R (adopted Sept. 29, 2006) [hereinafter *EC-Biotech Report*], at para. 4.157-4.158.

57 SPS Agreement, *supra* note 54, art. 3, para. 2.

basis and be based on an assessment of risk.[58] WTO jurisprudence makes clear that a country does not have to base their measure on majority science, but it does need to be supported by respected and qualified sources.[59] WTO jurisprudence also makes clear that that the risk assessment can take into account both qualitative and quantitative factors.[60] In terms of factors to take into account for risk assessment, the SPS Agreement Art. 5 requires members to take into account both scientific evidence and relevant economic factors, specifically:

> 2. In the assessment of risks, Members shall take into account available *scientific evidence*; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest — or disease — free areas; relevant ecological and environmental conditions; and quarantine or other treatment.
>
> 3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as *relevant economic factors*: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.[61](emphasis added)

Measures that comply with the SPS agreement are presumed to comply with the General Agreement on Tariffs and Trade (GATT), the major WTO agreement governing trade-in-goods.[62]

Despite SPS Agreement's requirements, many countries have blocked or limited their markets to GMO seeds, crops, feed, and/or food.[63] The United States successfully challenged an E.U.

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58 *Id.* art. 5, para. 2.

59 *See* WTO Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS/AB/R (adopted Jan. 16, 1998) [hereinafter *EC – Beef Hormones Report*]; *see also* Matthew Schaefer, *Food Safety Regulations, Cross Border Implications: A U.S. Perspective*, 24 Can.-U.S. L.J. 377, 381 (1998) [hereinafter Schaefer, Food Safety].

60 *See* Schaefer, Food Safety, *supra* note 59, at 381-382.

61 SPS Agreement, *supra* note 54, art. 5.

62 SPS Agreement, *supra* note 54, art. 2, para. 4.

63 *See, e.g.*, *Where Are GMO Crops and Animals Approved and Banned?*, GENETIC

moratorium on approving new GM crops in a WTO dispute settlement case, but some E.U. member states simply imposed individual moratoriums, rendering the victory illusory.[64] Another successful SPS case, this one against the E.U.'s ban on hormone-treated beef, was similarly fruitless, leading not to actual change in the E.U. ban but rather U.S. retaliation for a number of years followed by a compensation deal between the countries increasing the quota for U.S. hormone-free beef.[65] In both cases, the WTO Appellate Body rejected the E.U.'s invocations of the "precautionary principle." The SPS Agreement has its own formulation of the precautionary principle in Article 5.7:

> 7. In cases where relevant scientific evidence is insufficient, a Member may *provisionally adopt* sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall *seek to* obtain *the* additional information *necessary* for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.[66] (emphasis added)

Importantly, this formulation of the precautionary principle in Article 5.7 only allows provisional adoption of such measures and that additional information for a more objective assessment be sought within a reasonable time.[67] The E.U. did not even invoke Article 5.7 in the *Beef Hormones* case, presumably because it could

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LITERACY PROJECT, https://geneticliteracyproject.org/gmo-faq/where-are-gmo-crops-and-animals-approved-and-banned/ (last visited Sept. 15, 2023) [https://perma.cc/YU26-D24H].

64 *See* Giovanni Tagliabue, *The EU Legislation on "GMOs" Between Nonsense and Protectionism: An Ongoing Schumpeterian Chain of Public Choic*es, 8 GM CROPS & FOOD 57, 62–63, 73 (2017).

65 *See* OFF. OF THE U.S. TRADE REPRESENTATIVE, EXEC. OFF. OF THE PRESIDENT, 2022 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 196 (2022); *see also* Jorge Volero, *Commission Proposes to Redistribute Beef Quota to Please the US*, EURACTIV (Sept. 3, 2018), https://www.euractiv.com/section/economy-jobs/news/commission-proposes-to-redistribute-beef-quota-to-please-the-us/ [https://perma.cc/PYT8-ZCTL].

66 SPS Agreement, *supra* note 54, art. 5.7.

67 *See id.*

not meet those conditions.[68]

Thus, countries supportive of gene-edited crops and food cannot rely solely on the SPS agreement nor adjudication by the WTO dispute settlement system—especially with the WTO Appellate Body having collapsed[69]—to ensure that gene-edited crops do not face the same regulatory stigma and obstacles encountered by GM crops and food. Argentina, aware of this reality, put forward a "soft law" statement for pro-gene-editing regulation within the WTO SPS committee in 2019 that was supported by 13 countries (Argentina, Australia, Brazil, Canada, Colombia, the Dominican Republic, Guatemala, Honduras, Jordan, Paraguay, the United States, Uruguay, Vietnam) and the Secretariat of the Economic Community of West African States—an organization representing 15 countries on the African continent, including Nigeria and Ghana.[70] The statement recognizes the importance of agricultural innovation, in particular "precision biotechnology such as gene editing,"[71] and calls on governments to create policy and regulatory frameworks that "continue to foster innovation."[72] In addition to cooperative research and calls for public communication efforts in support of gene editing, the vast majority of the statement focuses on regulation principles:

- Given the differences internationally in approaches used to assess agricultural biotechnology, due consideration should be exercised by governments to avoid arbitrary and unjustifiable distinctions between end products derived from precision biotechnology and similar end products obtained through other production methods;
- To ensure appropriate science- and risk-based approaches consistent with the protection of human, animal and plant health and the environment, due consideration should be given to available scientific and technical information when updating existing

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68 Panel Report, *United States-EC Measures Concerning Meat and Meat Products (Hormones),* WTO Doc. WT/DS26/R/USA (adopted Aug. 18, 1997).

69 *See* Schaefer, *supra* note 8; Lester, *supra* note 6.

70 Request for Communication by Argentina, Australia, Brazil, Canada, the Dominican Republic, Guatemala, Honduras, Paraguay, the United States of America and Uruguay, *International Statement on Agricultural Applications of Precisions Biotechnology*, WTO Doc. G/SPS/GEN/1658/Rev.3 (Jan. 11, 2018) [hereinafter SPS Committee Statement].

71 *Id.* art. 2, para. 2.1.

72 *Id.*

regulatory frameworks or applying these frameworks to products of precision biotechnology, and when using available flexibility within existing regulatory frameworks for agricultural products;

• Regulatory approaches necessary to help ensure safety (of humans, animals, plants, and the environment) in respect of products derived from precision biotechnology should be science- and risk-based, transparent, predictable, timely, and consistent with relevant international trade obligations;

• Cooperative work by governments to minimize unnecessary barriers to trade related to the regulatory oversight of products of precision biotechnology, including the exploring of opportunities for regulatory and policy alignment, should be pursued where possible;

• This collaborative work should promote constructive dialogue with trading partners and agricultural stakeholders on potential trade issues related to precision biotechnology, so as to support open and fair trade and encourage research and innovation[.][73]

The first bullet point supports use of product-based regulation of gene-edited products. The calls in the second to last bullet point to explore "opportunities for regulatory and policy alignment" suggest countries should look at harmonization of regulatory standards and/or mutual recognition of gene-edited products approved in other countries. In essence, the statement is encouraging several types of provisions recommended later in this article for inclusion in binding U.S. trade agreements.

B. Cartagena Protocol

The Cartagena Protocol is concerned both with the impact on biodiversity and human health of living modified organisms (LMOs).[74] As its Preamble lays out:

> Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health; Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human

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73 *Id*. at para. 2.3.

74 Cartagena Protocol on Biosafety to the Convention on Biological Diversity, ch. XXVII, § 8a, Jan. 29, 2000, 2226 U.N.T.S. 208 [hereinafter Cartagena Protocol].

health . . .[75]

But the primary focus of the Protocol, as evidenced by its scope and stated objectives, is addressing adverse effects on biodiversity; risks to human health are addressed as a secondary consideration.[76] The scope of the protocol limits its application to "the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."[77] The stated objective of the Cartagena Protocol is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."[78] Thus, its focus is primarily on the impacts of "living modified organisms" ("LMOs") on biological diversity, but it also wants risks to human health taken into account. Importantly, the Protocol also proclaims a specific focus on the transboundary movements of these LMOs.[79] In this regard, as well as its secondary focus on human health, the Protocol overlaps to some degree with the WTO SPS agreement.

There is much debate over whether gene-edited crops would meet the definition of LMO and thus fall within the scope of the Protocol.[80] Under the Protocol, an LMO is "any living organism that possesses a novel combination of genetic material obtained through

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75 *Id.* at prmb.

76 *Id.* at art. 1, 4. The scope of the Protocol limits its application to "the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health." *Id.* art. 4. The stated objective of the Cartagena Protocol is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements." *Id.* art. 1.

77 *Id*. at art. 1.

78 *Id.*

79 *Id.* at art. 1, 4.

80 *See, e.g.,* Jochen Menz et al., *Genome Edited Crops Touch the Market: A View on the Global Development and Regulatory Environment*, 11 FRONTIERS IN PLANT SCI., Oct. 9, 2020, at 1, 2.

the use of modern biotechnology."[81] Some argue that using foreign DNA in the process of gene editing is sufficient to have the product meet the definition of LMO, while others argue that if no foreign DNA remains in a product, it should not be considered an LMO.[82]

And many of the scientist and NGOs debating that issue may not be paying sufficient attention to Vienna Convention Law of Treaties (VCLT) rules on treaty interpretation that require interpretation of a treaty to start with the ordinary meaning of the terms of the treaty in their context and in light of object and purpose.[83] One strong argument that gene-edited crops do not fall under the definition is that, while they involve nucleic acid techniques, these techniques may not be considered "modern biotechnology" under the Protocol because they do not "overcome natural physiological reproductive or recombination barriers."[84] If the organism is not the product of "modern biotechnology," then it is not an LMO. This ties in with the notion that gene editing is simply speeding up and making more efficient changes that could be done under more conventional methods. Further, even if a "foreign" gene remains, if it is the gene of the same/similar species or sexually compatible species, then this scenario could also be considered to not "overcome natural physiological reproductive or recombination barriers."[85] The Protocol's Annex III on risk assessment does seem to suggest that crops not containing foreign DNA or only the DNA of a closely akin species were not really at the heart of what was meant to be captured by the definition of LMO:

> To fulfil its objective, risk assessment entails, as appropriate, the following steps: (a) An identification of any novel genotypic and

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81 Cartagena Protocol, *supra* note 74, at art. 3(g).

82 *See* Menz et al*., supra* note 80, at 3 (discussing approaches of various countries).

83 *See* Vienna Convention on Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331, art. 31 [hereinafter VCLT].

84 Cartagena Protocol, *supra* note 74, at art. 3, sec. (i)(b). *But see* IUCN ENVTL. L. CTR., EXPLANATORY GUIDE TO THE CARTAGENA PROTOCOL ON BIOSAFETY 4698-103 (2003)), ("The question as to whether the genotype or phenotype of an organism could also have occurred naturally has no bearing on whether an altered organism is a LMO under the Protocol or not. Whether an organism is, or is not, a modified organism under the Protocol, is only dependent on the use of specific techniques defined by the Protocol as techniques of modern biotechnology (see Article 3(i)), to create a novel combination of genetic material.").

85 *Cartagena Protocol*, *supra* note 74, at art. 3(i)(b).

> phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health[.][86]

If gene-edited crops and food do not meet the definition of LMO, then the Protocol does not create any inconsistency with the SPS agreement on such products. However, if gene-edited crops and food are found to meet the definition of LMO, they would fall under the scope of the Protocol, creating potential inconsistencies with the SPS, primarily as regards different elaborations of the precautionary principle and different factors that can be taken into account in risk assessments.

The Protocol creates an advanced informed agreement requirement prior to "intentional introduction into the environment of the Party of import."[87] Because "intentional introduction into the environment" does "not refer to living modified organisms intended for direct use as food or feed, or for processing,"[88] advanced informed consent does not apply to LMOs that will be directly used for those purposes.[89] It is left up to each country to regulate those used directly for food or feed or processing, although the Protocol establishes a multilateral information exchange mechanism centered around the Biosafety Clearing-House so that importing countries can check the Clearing-House for new LMOs.[90] Intentional introduction into the environment includes "the use of the LMO in question in field trials in the Party of import; the commercial scale growing of agricultural LMOs; or the deliberate release of genetically modified micro-organisms into the environment."[91] Therefore, certainly seeds would be covered by the intentional introduction definition.

Obtaining the advanced informed agreement requires a number of procedural steps. Under the Protocol, the process of obtaining a decision from the importing country can take up to a year—as the importing country has 90 days to give receipt of notification of an

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86 *Id.* annex III, § 8(a).

87 *Id.* at art. 7, § sec. 1.

88 *Id.* at art. 7, § 2.

89 *See* Steve Charnovitz, *The Supervision of Health and Biosafety Regulation by World Trade Rules*, 13 TULANE ENV'T L. J. 271, 299 (2000).

90 *See* Cartagena Protocol, *supra* note 74, at art. 11.

91 *See* IUCN ENV'T L. CTR., *supra* note 84, at 68.

application[92] and a further 270 days to make a decision.[93] The Protocol mandates risk assessment for the advanced informed agreement decision and allows the importing party to carry out the risk assessment itself[94] (although it can require the notifier (applicant) to bear the costs)[95] or it can "require the exporter to carry out the risk assessment."[96] There are exemptions for contained use and transit through countries from the advanced informed agreement requirement,[97] but the Protocol does not prohibit regulation by the relevant country either.[98]

Fortunately, the Protocol also allows for simplified procedures that obviate the need for advanced informed agreement:

> A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:
>
> (a)Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and
>
> (b)Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.[99] Additionally, the Protocol allows for bilateral and regional agreements and allows imports to take place under those agreements.[100] Specifically, parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and "provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol."[101]

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92 *Cartagena Protocol*, *supra* note 74, at art. 9, § 1.

93 *Id.* at art. 10, § 3.

94 *Id.* at art. 15.

95 *Id.* at art. 15, § 3.

96 *Id.* at art. 15, § 2.

97 *Id.* at art. 13, § 1(b).

98 *Id.* at art. 14, § 4.

99 *Id.* at art. 13, § 1.

100 *Id.* at art. 14, § 1.

101 *Id*.

There are open questions as to whether these agreements and arrangements can refer to those with non-parties to the Protocol and specifically what would satisfy the "not result in lower level of protection" language.[102] However, since the Protocol allows for simplified procedures, advance informed consent is not likely to be absolutely required under any such agreements and the Protocol makes clear it does "not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements."[103] Further, "any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision."[104] It is clear from the generally pro-gene-editing stance taken within the Americas, discussed further below, that the Cartagena Protocol, either because of coverage issues or flexibilities, permits countries to have pro-gene-editing regulatory approaches to gene-edited crops and food. Indeed, countries might be able to use flexibilities to further liberalize their gene-editing regulations.

However, while the Protocol may allow for such pro-gene-editing trade regulations, it does not necessarily promote such regulations globally. To the extent there are coverage overlaps between the SPS agreement and the Cartagena Protocol, one central difference between the two agreements is that the Cartagena Protocol has a much broader conception of the precautionary principle than the SPS agreement. Article 10(6) of the Protocol states:

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question . . . in order to avoid or minimize such potential adverse effects.[105]

Similar language is used in Article 11(8) for LMOs to be used

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102 *See* IUCN ENV'T L. CTR., *supra* note 84, at 99.

103 Cartagena Protocol, *supra* note 74, art. 14, § 3.

104 *Id.* at art. 14, § 4.

105 *Id.* at art. 10, § 6.

as feed or food or for processing.[106] The Protocol does not characterize these measures as "provisional" nor impose an obligation to obtain more information providing for a more objective assessment of risk within a reasonable period of time and thus is much looser than WTO SPS Article 5.7.[107] The Protocol also allows consideration of "socioeconomic" factors rather than "economic" factors in conducting a risk assessment.[108] It is therefore much looser than the SPS Agreement's provision in this regard as well.[109]

C. Relationship of Cartagena Protocol to the WTO SPS Agreement

A collision between the Cartagena Protocol and the WTO SPS Agreement could occur with respect to different formulations of the precautionary principle or risk assessment factors. The WTO Agreements entered into force in 1995[110] whereas the Cartagena Protocol entered into force in 2003.[111] 164 nations/territories are party to the WTO[112] and 173 are party to the Cartagena Protocol.[113] One-hundred and forty-eight are parties to both agreements.[114] Sixteen nations/territories are parties to WTO but not the Cartagena

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106 *Id*. at art. 11, § 8.

107 SPS Agreement, *supra* note 54, at art. 5, para. 7.

108 Cartagena Protocol, *supra* note 74, art. 26. At COP-MOP8, the CBD Secretariat published a revised set of non-binding guidelines on risk assessment, but this has not been formally adopted. As regards socioeconomic factors, the COP-MOP9/10 simply took note of draft guidance developed by the AHTEG and requested continued information sharing on the issue. *See* Convention on Biological Diversity, What Has Been Done on Socio-Economic Considerations, *available at* https://bch.cbd.int/protocol/cpb_art26_info.shtml.

109 *Compare* Cartagena Protocol, *supra* note 74, art. 26 with SPS Agreement, *supra* note 54, at art. 5(3).

110 *See Understanding the WTO: Basics*, WTO, https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm (last visited Sept. 3, 2023) [https://perma.cc/DE3G-WU64].

111 *The Cartagena Protocol: About the Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY (May 5, 2021), https://bch.cbd.int/protocol/background/ [https://perma.cc/KZ27-89CL].

112 See *Understanding the WTO: The Organization*, WTO https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Sept. 3, 2023) [https://perma.cc/FQ3F-27LG].

113 *Parties to the Cartagena Protocol and its Supplementary Protocol Liability and Redress*, CONVENTION ON BIOLOGICAL DIVERSITY, https://bch.cbd.int/protocol/parties/ (last visited Sept. 3, 2023) [https://perma.cc/F5G8-MYPJ].

114 *See id.*; *Understanding the WTO: The Organization, supra* note 112.

Protocol. Twenty-six are party to the Cartagena Protocol but not WTO.

Countries/Territories that are Party to WTO but Not Cartagena	Countries/Territories that are Party to Cartagena but not to WTO
1. Argentina W:1995 2. Australia W:1995 3. Brunei Darussalam W:1995 4. Canada W:1995 5. Chile W:1995 6. Haiti W: 1996 7. Iceland W:1995 8. Israel W:1995 9. Liechtenstein W:1995 10. Macao, China W:1995 11. Nepal W:2004 12. Russian Federation W: 2012 13. Singapore W:1995 14. Chinese Taipei W:2002 15. United States W:1995 16. Vanuatu W:2012	1. Algeria C:2004 2. Azerbaijan C:2005 3. Bahamas C:2000 4. Belarus C:2003 5. Bhutan C:2003 6. Bosnia and Herzegovina C:2009 7. Comoros C:2009 8. Democratic People's Republic of Korea C:2003 9. Eritrea C:2005 10. Ethiopia C:2000 11. Iran C:2004 12. Iraq C:2014 13. Kiribati C:2004 14. Lebanon C:2013 15. Libya C:2005 16. Marshall Islands C:2003 17. Nauru C:2003 18. Niue C:2003 19. Palau C:2003 20. Serbia C:2006 21. Somalia C:2010 22. Palestine C:2015 23. Sudan C:2005 24. Syrian Arab Republic C:2004 25. Turkmenistan C:2008 26. Uzbekistan C:2020

If two international agreements are in conflict (i.e., cannot be reconciled), then several rules may come into play to determine

which agreement governs the obligations of countries that are parties to both agreements. Of course, not all relevant gene-editing countries are parties to both agreements. If there is a dispute between two countries concerning regulation of gene-edited products and those countries are only jointly party to one treaty, it is the jointly partied treaty which governs as treaties only create rights and obligations for parties to the treaty.[115] Several gene-editing-important countries are party to the WTO but not the Cartagena Protocol, including Argentina, Australia, Canada, Chile, and the United States.[116] None of the 26 countries that are party only to the Cartagena Protocol are major export markets.[117]

If there is a dispute between countries party to both agreements, then it needs to be determined which agreement controls. One potential resolution is through the later-in-time rule, which finds specific expression in the Vienna Convention on the Law of Treaties (VCLT) Art 30:

> 3. When all the parties to the earlier treaty are parties also to the later treaty but the earlier treaty is not terminated or suspended in operation under article 59, the earlier treaty applies only to the extent that its provisions are compatible with those of the latter treaty.[118]

Another avenue of resolving the conflict could be found through *lex specialis*, a rule providing that the specific prevails over the general,[119] although it does not find specific expression in the VCLT. The SPS Agreement dealing with food safety standards is arguably more specific than the Cartagena Protocol dealing with transboundary movement of LMOs.

In some treaties, a so-called "savings clause" is included protecting an earlier treaty from being superseded by the latter treaty. VCLT Art. 30 recognizes this in paragraph two: "When a treaty specifies that it is subject to, or that it is not to be considered

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115 VCLT, *supra* note 83, at art. 30(4) & 34.

116 *See Understanding the WTO: The Organization, supra* note 112.

117 *Exports by Country 2023*, World Population Review, https://worldpopulationreview.com/country-rankings/exports-by-country (last visited Sept. 3, 2023) [https://perma.cc/LX3Y-5W8L].

118 VCLT, *supra* note 83, at art. 30(3).

119 *See, e.g.,* Marco Milonovic, *The Genesis of Lex Specialis*, EJIL: TALK! (April 30, 2014), https://www.ejiltalk.org/the-genesis-of-lex-specialis/ [https://perma.cc/H42P-RBQL].

as incompatible with, an earlier or later treaty, the provisions of that other treaty prevail."[120] It is unclear whether the Cartagena Protocol included a "savings clause" for the WTO SPS Agreement. The negotiators of the Cartagena Protocol could not come to definitive agreement on the relationship between the Protocol and WTO SPS Agreement.[121] However, the following three sentences were included in the Preamble to the Protocol:

> Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development. Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements. Understanding that the above recital is not intended to subordinate this Protocol to other international agreements.[122]

The first sentence is aspirational—that trade agreements like the WTO agreements and environment agreements like the Cartagena Protocol should be mutually supportive. The second sentence appears to create a savings clause for the SPS agreement but is somewhat undermined by the third sentence. The fact that these clauses are placed in the preamble rather than the text of the agreement itself further clouds the impact of these clauses as typically preambular language does not create legal obligations.[123] However, it is unclear that a savings clause would need to be put in the text of an agreement itself. Further, the principle of effectiveness in treaty interpretation, thought to be part of customary international law, requires a reading giving effect to language rather than an interpretation denying meaning to language.[124] This principle suggests the three sentences collectively should operate as a savings

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120 VCLT, *supra* note 83, at art. 30, para. 2.

121 *See* Secretariat of the Convention on Biological Diversity, THE CARTAGENA PROTOCOL ON BIOSAFETY: A RECORD OF THE NEGOTIATIONS 110 (Appendix I: Deleted Draft Articles – Relationship to Other International Agreements), available at https://www.cbd.int/doc/publications/bs-brochure-03-en.pdf.

122 Cartagena Protocol, *supra* note 74, at prmb.

123 *See, e.g.*, Max H. Hulme, *Preambles in Treaty Interpretation*, 164 U. PA. L. REV. 1281, 1285–86 (2016).

124 *See, e.g.*, Daniel Rietiker & Sofie Steller, Book Review, VOLKERRECHTSBLOG (Oct. 10, 2022), https://voelkerrechtsblog.org/the-principle-of-effectiveness-and-its-overarching-role-in-the-interpretation-and-application-of-the-echr [https://perma.cc/T7ZA-6VFT] (reviewing GEORGIOS SERGHIDES, THE PRINCIPLE OF EFFECTIVENESS: AND ITS OVERARCHING ROLE IN THE INTERPRETATION AND APPLICATION OF THE ECHR (2022)).

clause; otherwise they have no effect. However, a rebuttal to this is that the preambular language is simply hortatory language that seeks to minimize the potential conflicts between the two agreements (despite the potential for a few such conflicts as with the different formulations of the precautionary principle and different factors that can be considered in a risk assessment, as discussed above).

A separate issue is what agreement would prevail in a WTO dispute settlement case. In Article 3.2 of the WTO Dispute Settlement Understanding, it states that the dispute settlement system "serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements."[125] WTO jurisprudence in *EC-Measures Affecting the Approval and Marketing of Biotech Products* ("*EC-Biotech*") indicates that the WTO Appellate Body and panels will "take into account" another international agreement when interpreting WTO agreements as is permitted by VCLT Art. 31(3)(c) but only where all WTO members are parties to the other agreement.[126] VCLT Art. 31(3)(c) provides: "There shall be taken into account, together with the context: . . . (c) Any relevant rules of international law applicable in the relations between the parties."[127] The panel in the *EC-Biotech* case indicated that "the parties" refers to all the parties of the WTO.[128] However the panel made clear that it was not ruling on a situation in which parties to a dispute settlement case are all parties to the other international agreement, even though not all WTO members are parties to the other international agreement, and the parties to the dispute all agreed that the other international agreement should be

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125 Understanding on Rules and Procedures Governing the Settlement of Disputes art. 3, para. 2, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU].

126 *EC-Biotech* Report, *supra* note 56, para. 7.52.

127 VCLT, *supra* note 83, art. 30, para. 3(c).

128 *See EC-Biotech* Report, *supra* note 56, paras. 7.68, 7.74, 7.75. The panel made clear that it was not ruling on a situation in which the parties to a dispute settlement case were all parties to the other international agreement in question and the parties to the dispute all agreed that the other international agreement should be taken into account. *See id.*

taken into account.[129] The panel further noted that it could look to other international agreements as "evidence of the ordinary meaning of terms used in a treaty" but there was no obligation to do so, particularly where other evidence was already abundant.[130] The net result is that the WTO panel in *EC-Biotech* refused to take account of or look at the Cartagena Protocol since none of the plaintiffs in the case —United States, Argentina, and Canada—were parties to the Protocol,[131] and thus by definition not all WTO members were party to the Protocol (indeed 16 countries are parties to WTO but not the Cartagena Protocol). There is no indication yet in WTO jurisprudence that the Appellate Body or panels will directly apply these hierarchy rules in the VCLT such that a non-WTO agreement applicable between the parties to a dispute prevails over WTO commitments. Indeed, any such approach arguably would run counter to DSU Article 3.2.

Informal means of cooperation between the institutions of the two agreements can also be beneficial but unlikely to resolve fully any inconsistencies between the two agreements. The Convention on Biological Diversity ("CBD")'s Conference of the Parties-Meeting of the Parties ("COP-MOP") has granted observer status to the WTO SPS Committee, but apparently the SPS Committee has not been involved yet in many meetings.[132] Conversely, the CBD Secretariat has been granted observer status in the WTO Committee on Trade and Environment ("CTE"), and furnishes the WTO Secretariat "with a summary of the decisions that have been reached by the parties to the Protocol." ^?)However, with the WTO Doha Round negotiations collapse in 2015,[133] the collaboration through the CTE has not been very significant. Further, the CBD has not been able to gain observer status in the WTO SPS committee, apparently due to objections from some WTO members.[134]The

129 *See id.*

130 *See id.* paras. 7.92–7.93.

131 *See supra* notes 110-113 and accompanying text and chart.

132 *See Cooperation with the WTO*, CONVENTION ON BIOLOGICAL DIVERSITY (Mar. 29, 2023), https://www.cbd.int/incentives/coop-wto.shtml [https://perma.cc/C3GT-J3SH] (showing as an example of cooperation an invitation for the SPS Committee to look into the risks of invasive species from COP9 that took place in 2008 with no more recent examples given).

133 *See The Doha Round Finally Dies a Merciful Death*, FINANCIAL TIMES, Dec. 21, 2015.

134 *Cooperation with the WTO*, *supra* note 132.

Codex Alimentarius Commission does have observer status, as does the International Plant Protection Convention, the World Health Organization (WHO), the United Nations (UN) Conference on Trade and Development, and the International Organization for Standardization.[135] While these informal modes of cooperation can be beneficial, they alone will not cure the obstacles that GM crops and food face, nor the barriers gene-edited foods face.

Renegotiation of either agreement is also not practical or feasible. The WTO's negotiation arm is severely damaged with no major negotiating round having concluded since 1994,[136] although some modest agreements were concluded at the 12th Ministerial Conference (MC-12) in 2022[137] and negotiations on a digital trade plurilateral are proceeding.[138] Therefore, gene-editing-allied countries cannot rely on pre-existing global frameworks to maximize global trade of gene-edited products.

D. Enhanced U.S. FTA and Non-Comprehensive Bilateral Trade Deals Encouraging Approval of and Trade in Gene-Edited Crops and Food

The United States and gene-editing-allied countries can create a favorable regulatory environment for such crops and food through regional and bilateral new-styled and non-comprehensive negotiations. These negotiations are already underway and can directly address agriculture biotechnology, including specifically gene-edited crops and food. Existing negotiations can be supplemented with issue specific negotiations with key countries in various regions of the globe. The question is whether the United States-Mexico-Canada Agreement ("USMCA") or China Phase I agreement, both of which entered into force in 2020, provide the appropriate models to utilize or whether bolder provisions should

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135 WTO SPS Committee, International Intergovernmental Organizations Observer Status, WTO Doc. G/SPS/W/78/Rev. 15, February, 15, 2021.

136 *See* Schaefer, *supra* note 8.

137 In an overambitious description of outcomes, *see WTO Members Secure Unprecedented Package of Trade Outcomes at MC12*, WTO (June 17, 2022), https://www.wto.org/english/news_e/news22_e/mc12_17jun22_e.htm [https://perma.cc/7GQA-NGP9].

138 *See E-Commerce Co-Convenors Call on Negotiators to Intensify Efforts, Exercise Flexibility,*. WTO (Sept. 29, 2023) https://www.wto.org/english/news_e/news23_e/jsec_29sep23_e.htm [https://perma.cc/WM79-ZRPJ].

be considered in future agreements.

1. The United States-Mexico-Canada (USMCA) Agreement

The USMCA defines agricultural biotechnology[139] and modern biotechnology[140] and is the first U.S. FTA to do so. This comes as no surprise given that it is the first concluded FTA by the United States since the Columbia and South Korean FTAs that entered into force in 2012 but for which negotiations concluded many years earlier in 2007.[141] The United States Trade Representative ("USTR") Fact Sheet for the USMCA touts as a "key achievement," "Setting Unprecedented Standards for Agricultural Biotechnology."[142] Specifically, the USTR fact sheet claims the agreement "covers all biotechnologies, including new technologies such as gene editing, whereas the Trans-Pacific Partnership text covered only traditional rDNA technology."[143]

The USMCA's definition of agricultural biotechnology is:

> technologies, including modern biotechnology, used for the deliberate manipulation of an organism to introduce, remove, or modify one or more heritable characteristics of a product for agriculture and aquaculture use and that are not technologies used in traditional breeding and selection.[144]

In turn, modern biotechnology is "the application of: (a) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles; or (b) fusion of

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139 Agreement Between the United States of America, The United States of Mexico, and Canada ch. 3, sec. B, art. 3.12, Jul. 1 2020, OFF. OF THE U.S. TRADE REPRESENTATIVE, https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between [https://perma.cc/69AX-XRG4] [hereinafter USMCA].

140 *Id.*

141 *See* Congressional Research Service, *The U.S.-Columbia Free Trade Agreement: Background and Issues*, May 4, 2002, at 1, available at http://www.sice.oas.org/tpd/and_usa/Studies/USA_COL_FTA_Rpt_2022_e.pdf; USTR, *U.S.-Korea Free Trade Agreement*, available at https://ustr.gov/trade-agreements/free-trade-agreements/korus-fta.

142 *United States-Mexico-Canada Trade Fact Sheet: Strengthening North American Trade in Agriculture*, OFF. OF THE U.S. TRADE REPRESENTATIVE [hereinafter *USTR USMCA Fact Sheet*], https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/fact-sheets/strengthening (last visited Sept. 3, 2023) [https://perma.cc/G9QB-VCBX].

143 *Id.*

144 USMCA, *supra* note 139, ch. 3, § B, art. 3.12.

cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection."[145] This would include gene-editing techniques, given USTR's explanatory fact sheet,[146] yet interestingly, the definition closely tracks that of the Cartagena Protocol in which context there is a debate over whether gene-edited products are covered.[147] Nonetheless, treaty interpretation looks at not just the text of an agreement but object and purpose as well and can even turn to negotiation records in cases of ambiguity,[148] so there is no doubt gene editing is covered by the USMCA definition.

The USMCA does not require Parties to mandate an authorization process in order for an agricultural biotechnology product to be placed on the market.[149] The three countries recognize the importance of biotechnology products and included requirements to avoid the "likelihood of disruptions to trade in products of agricultural biotechnology,"[150] specifically:

> (a) each Party shall continue to encourage applicants to submit timely and concurrent applications to the Parties for authorization, if required, of products of agricultural biotechnology; (b) a Party requiring any authorization for a product of agricultural biotechnology shall: (i) accept and review applications for the authorization, if required, of products of agricultural biotechnology on an ongoing basis year-round, (ii) adopt or maintain measures that allow the initiation of the domestic regulatory authorization process of a product not yet authorized in another country, (iii) if an authorization is subject to expiration, take steps to help ensure that the review of the product is completed and a decision is made in a timely manner, and if possible, prior to expiration, and (iv) communicate with the other Parties regarding any new and existing authorizations of products of agricultural biotechnology so as to improve information

145 *Id.*

146 *USTR USMCA Fact Sheet*, *supra* note 142.

147 *See generally* Cartagena Protocol, *supra* note 74; *see also supra* notes 80-85 and accompanying text.

148 *See* VCLT, *supra* note 83, arts. 31-32.

149 USMCA, *supra* note 139 at ch. 3, § B, art. 3.14, para. 2.

150 *Id.* at ch. 3, § B, art. 3.14, para. 4.

exchange.[151]

The USMCA also contains provisions to address low-level-presence (LLP) occurrences where low levels of recombinant DNA plant materials that have passed a food safety assessment in one country and are inadvertently present in food or feed in an importing country that has not made a safety determination.[152] The goal is to not halt significant trade merely because of an LLP occurrence.[153] Parties are required to exchange information concerning the LLP occurrence.[154] Again, the main emphasis is on not having a regulatory over-reaction to the LLP occurrence.[155] The obligations hitting most closely on this objective are paragraph 3 requiring that a Party facing an LLP:

> (c) ensure that the LLP Occurrence is managed without unnecessary delay and that any measure applied to manage the LLP Occurrence is appropriate to achieve compliance with the importing Party's laws and regulations and takes into account any risk posed by the LLP Occurrence; and (d) take into account, as appropriate, any relevant risk or safety assessment provided, and authorization granted, by another Party or non-Party when deciding how to manage the LLP Occurrence.[156]

The USMCA also establishes a working group on agricultural biotechnology that will involve representatives from all three countries.[157] The working group will seek to exchange information on regulatory approaches,[158] facilitate trade in agricultural biotechnology products,[159] seek common approaches to LLP

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151 *Id.* at ch. 3, § B, art. 3.14, para. 4.

152 *Id.* at ch. 3, § B, art. 3.12 (Low Level Presence (LLP) Occurrence means "low levels of recombinant deoxyribonucleic acid (DNA) plant materials that have passed a food safety assessment according to the Codex Guideline for the Conduct of a Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) in one or more countries, which may on occasion be inadvertently present in food or feed in importing countries in which the food safety of the relevant recombinant DNA plant has not been determined."); *See also id.* at ch. 3, § B, art. 3.15.

153 *See supra* note 152, at ch. 3, § B, art. 3.15.

154 *See id.* at ch. 3, § B, art. 3.15, paras. 2-3.

155 *See id.* at ch. 3, § B, art. 3.15.

156 *See id.* at ch. 3, § B, art. 3.15, para. 3.

157 *Id.* at ch. 3, § B, art. 3.16, para. 1.

158 *Id.* at ch. 3, § B, art. 3.16, para. 2(c).

159 *Id.*

occurrences,[160] and "coordinate efforts to advance regulatory approaches and trade policies that are transparent, and based on science and on risk for products of agricultural biotechnology in other countries and in international organizations."[161]

However, there are no provisions for harmonization (around the U.S. approach to gene editing) nor towards mutual recognition in the USMCA. Rather, there are only references to coordinate efforts to advance transparent, science-based regulation and to take into account approvals by other countries in reacting to LLP events. Pursuit of bolder provisions such as harmonization and/or mutual recognition in future agreements could increase trade and investment in gene-edited crops and food and more rapidly extend the benefits of such crops and food.

2. China Phase I Trade Agreement

The China Phase I deal's agriculture negotiations took dozens of sessions between the United States and China, resolving over 50 issues.[162] One issue that remains unresolved in terms of implementation is the issue of agriculture biotechnology. Chapter 3 of the so-called Phase I trade agreement between the United States and China deals with agriculture[163] and in its preamble the countries take note of

> the ability of agricultural biotechnology to improve lives by helping to feed growing populations, by reducing the environmental impact of agriculture, and by promoting more sustainable production, [and] intend to maintain, for products of agricultural biotechnology, science- and risk-based regulatory frameworks and efficient authorization processes, in order to facilitate increased trade in such products[.][164]

In Annex 16, the parties further express their intent "to take steps to enhance engagement with the public concerning agricultural biotechnology and public awareness of scientific

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160 *Id.* at ch. 3, § B, art. 3.16, para. 2(d).

161 *Id.* at ch. 3, § B, art. 3.16, para. 3.

162 Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China, Jan. 15, 2020, OFF. OF THE U.S. TRADE REPRESENTATIVE, https://ustr.gov/countries-regions/china-mongolia-taiwan/peoples-republic-china/phase-one-trade-agreement/text [https://perma.cc/KLC2-QLC2] [hereinafter China Phase I Deal].

163 *Id.* at ch. 3.

164 *Id.* at ch. 3, para. 1(d).

information relevant to agricultural biotechnology, . . . with the aim of building public confidence in, and acceptance of, the use of safe biotechnology in agriculture and the food system."[165] This is broad language but important given that legal commitments alone have not been sufficient to allow prompt approval of and allowance of trade in GM products in other major markets like the E.U. because of a lack of public confidence. With respect to China specifically, a recent study of nearly 2,000 respondents across a variety of stakeholder groups found that "nearly 80% of the Chinese public are accepting foods labeled as not containing GM ingredients, 57% are accepting foods without labeling, and ~40% are accepting GM-labeled foods."[166] The study also found that the more aware a person is regarding GM products, the more likely they are to accept the product and the less confidence a consumer has in their government the less likely they are to accept GM food.[167]

The heart of the U.S.-China Phase I deal on agricultural biotechnology follows in the next paragraph that requires China to:

> implement a transparent, predictable, efficient, science- and risk-based regulatory process for safety evaluation and authorization of products of agricultural biotechnology. For agricultural biotechnology products for feed or further processing, China shall significantly reduce, to no more than 24 months, the average amount of time between: (a) the submission of a formal application for authorization of such a product; and (b) the final decision on approval or disapproval of the product. China shall base its safety evaluation procedures on the relevant international standards and recommendations of Codex and the International Plant Protection Convention [IPPC]. China shall base any safety evaluation that it conducts on scientific data and information obtained using appropriate methods and analyzed using appropriate statistical techniques.

These obligations go beyond the WTO SPS agreement by specifically limiting the approval process for such products to 24 months[168] and requiring that its safety evaluation procedures be

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165 *Id.* at annex 16, para. 1.

166 Yawei Zhao et al., *Chinese Public's Awareness and Attitudes Toward Genetically Modified Foods with Different Labeling*, NATURE: NPJ SCIENCE OF FOOD, Sept. 26, 2019, at 1.

167 *Id.*

168 China Phase I Deal, *supra* note 162, annex 16, para. 2.

based on Codex and the International Plant Protection Convention ("IPPC") rather than simply giving a presumption of conformity if standards by those organizations are used.[169]

Additionally, the agreement requires timely information be given to any biotechnology approval applicant on deficiencies in applications at various stages, including within five days of the initial application[170] and within twenty days of any National Biosafety Committee (NBC) meeting at which insufficient information is found.[171] Additionally, at least two NBC meetings per year are required, and more as needed given the volume of applications.[172] Authorization periods granted for these agricultural biotechnology products must be a minimum of five years in length.[173]

On LLP events, the US-China Phase I language is similar to that of the USMCA, namely China is required to "(c) ensure that the LLP occurrence is managed without unnecessary delay; and (d) take into account any relevant risk or safety assessment provided, and authorization granted, by the United States or any foreign country when deciding how to manage the LLP occurrence."[174] However, the Phase I deal adds that "China shall evaluate inadvertent or technically unavoidable LLP occurrences on a case-by-case basis to minimize trade disruptions."[175]

Yet, even strong provisions for agricultural biotechnology in U.S. trade agreements require enforcement to ensure compliance. USTR's 2023 National Trade Estimates Report on Foreign Trade Barriers expresses deep concerns with China's implementation of Phase I agriculture biotechnology commitments:

> China's approach to agricultural biotechnology remains among the most significant commitments under the Phase One Agreement for which China has not demonstrated full implementation. There remains a significant lack of transparency regarding the procedures for convening meetings of the NBC, including regarding dates and agenda items for these meetings,

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169 *Id.* at annex 16, para. 2.

170 *Id.* at annex 16, para. 4(a).

171 *Id.* at annex 16, para. 4(c).

172 *Id.* at annex 16, para. 4(e).

173 *Id.* at annex 16, para. 5.

174 *Id.* at annex 16, para. 8(c)–(d).

175 *Id.* at annex 16, para. 9.

> and the process for notifying applicants of outcomes and for soliciting additional information to support product applications. While the NBC is required to meet at least two times each year, the meetings are not held pursuant to a regular schedule, and information about the meetings is not widely shared with the public in a transparent and predictable manner. In addition, in conducting its approval process, China continues to ask for information that is not relevant to a product's intended use or information that applicants have previously provided. For this and other reasons, China has not reduced the average time for its approval process for agricultural biotechnology products for feed or further processing to no more than 24 months, as it had committed to do[.][176]

As with the USMCA, there is no movement in the US-China Phase I trade deal towards harmonization (around the U.S. approach to gene editing) nor towards mutual recognition.[177] Pursuit of such bolder provisions in future agreements could increase trade and investment in gene-edited crops and food and more rapidly extend the benefits of such crops and food. Instead, the USMCA and US-China Phase I deal represent first steps in promoting trade in gene-edited crops and food. As discussed further, future deals can include additional, bolder provisions on approval and labeling, including possible harmonization around U.S. regulatory approaches or a degree of mutual recognition, to achieve more open trade and greater economies of scale. Naturally, provisions on particular bilateral or trilateral irritants in trade in gene-edited crops and food can also be included.

IV. Domestic GM and Gene-Edited Crop and Food Regulation Across the Globe

As we turn to domestic national regulation of GM and gene-edited crops that are currently in place around the globe, it is important to realize that regulatory predictability and timeliness are important if gene-edited technology is going to have a "democratizing" effect by drawing in new developers—including

176 OFF. OF THE U.S. TRADE REPRESENTATIVE, EXEC. OFF. OF THE PRESIDENT, 2023 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 73 (2023) [Hereinafter 2023 NATIONAL TRADE ESTIMATE REPORT].

177 *See generally* US-China Phase I Trade Deal, *supra* note 162.

SMEs—and providers from a much broader array of countries.[178] GM crops in most countries are subject to additional reviews regarding the environment and food safety prior to field trials and consumer consumption to determine potential impacts of foreign DNA or other genetic modification.[179] The E.U. and the United States were the first to regulate GM crops and basically represent two distinct regulatory approaches: the precautionary principle and substantial equivalence, respectively.[180]

One study looked at whether countries regulating GM crops were "product-based" v. "process-based" and found that of 24 countries producing GM crops, their respective regulatory approaches were roughly equally divided.[181] Even when limiting examination to the top 10 GM producing countries, the regulatory approaches were roughly equally divided.[182] If the definition of GM was based on a final product or the GM organism that possesses a specific genetic status (such as 'a novel combination of genetic material obtained through the use of modern biotechnology'), the concept was deemed to be a product-based regulation.[183] However, categorizing a regulation as either product-based or process-based is fraught with difficulty. The study's product-based definition is basically lifted from the Cartagena Protocol and the latter half of the definition is referring to process ("through the use of modern biotechnology").[184] Further, in online discussion forums created by the CBD Secretariat,[185] it is clear that some scientists and NGOs look at the Cartagena Protocol definition from the perspective of process (i.e. all gene edited products are captured) rather than from

178 *See* Whelan et al., *supra* note 43, at 7 ("Gene editing is perhaps the newest paradigm shift of the present-day industrial revolution that encompasses biotechnology[.]").

179 Tetsuya Ishii & Motoko Araki, *A Future Scenario of the Global Regulatory Landscape Regarding Genome-Edited Crops*, 8 GM CROPS & FOOD 44, 45 (2017).

180 *See* Vigani & Olper, *supra* note 17, at 44.

181 *See* Ishii & Araki, *supra* note 179, at 46 (noting that eleven of the studied countries were deemed to adopt product-based regulations whereas thirteen were deemed to have process-based regulations).

182 *See* Ishii & Araki, *supra* note 179, at 47.

183 *See id.* at 45–46.

184 *Compare id*. *with* Cartagena Protocol, *supra* note 74, art. 3(g), (i).

185 *See generally*, Convention on Biological Diversity, *Discussion Forums*, available at https://bch.cbd.int/onlineconferences/portal_art26/se_forum_archive.shtml (but note that this particular discussion is no longer available).

perspective of the final product. In any event, and in contrast, if a regulatory definition focused on the process of genetic modification ("such as 'the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'"), the concept was regarded as a process-based regulation in the study.[186] This definition also encounters complexities since one argument is that gene editing often achieves what could be done through conventional means, only more quickly. The organization Food Safety Australia New Zealand (FSANZ) discussed the benefits and drawbacks of the two competing approaches in a recent report released in 2019.[187] Importantly, the report emphasizes that utilizing a product-based approach better allows a regulation to be applied commensurate with risk while process-based regulations risk having identical or similar products regulated differently.[188]

The world currently has a patchwork of differing national regulatory regimes creating difficulties for trade in such products. Two of the largest markets in the world, the United States and the European Union currently maintain polar opposite approaches. The long-standing European battleground over new plant breeding technologies is examined first, followed by the leaders in pro-gene-editing regulation, Argentina and the United States, and subsequently a survey of every major region of the world.

A. The Long-Standing European Battleground

The E.U. has long been hostile to GM crops. It has relied on precautionary principle justifications in the area of SPS measures more generally as evidenced by the continued ban on hormone-treated beef despite losing a case before the WTO Appellate Body over two decades ago.[189] Indeed, the precautionary principle is enshrined in the E.U.'s "constitution"—the Treaty on the Functioning of the European Union.[190] Europe's regulatory

186 *See* Ishii & Araki, *supra* note 179, at 46.

187 *See* FOOD STANDARDS AUSTRALIA NEW ZEALAND, FINAL REPORT: REVIEW OF FOOD DERIVED USING NEW BREEDING TECHNIQUES 17 (2019) (" . . . because some NBTs can result in foods that are identical or equivalent to conventional foods, a further disadvantage of process-based definitions is that they can result in identical products being regulated differently.") [hereinafter FSANZ, Final Report].

188 *See id.*

189 *See* EC- Beef Hormones Report, *supra* note 59.

190 *See* Treaty on the Functioning of the European Union, art. 191, Jun. 7, 2016, 2016 O.J. (C 202) 132.

environment is more subject to influence by consumer (mis)perception than in the United States, although cultural differences exist that can partially explain some of the asynchronous perceptions of technological change too.[191]

One of the E.U.'s regulatory approaches consists of a pre-market authorization regime for GMOs, which are subject to an environmental and human health risk assessment. In this context, a GMO is defined as 'an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.'[192] After authorization, GMOs are subject to traceability, labelling, monitoring, and liability obligations.[193] As of 2023, the United States is tracking 35 agricultural biotechnology product applications (including renewals) of corn, soybean, canola, sugar beet, and cotton submitted to the EU.[194] Of those applications, 30 are waiting for a scientific review by the European Food Safety Authority (EFSA) and 5 are waiting for approval action by the Commission.[195] The average length for an approval recently is six years, well beyond the 12 months called for in E.U. regulation[196]– and this delayed process is thought to cost U.S. producers $2 billion/year.[197] These delays create an asynchronous approval situation between the two largest markets in the world and therefore raises the risk of low-level presence events. Additionally, similar problems exist with other large U.S. agricultural export markets (China, Canada, and Mexico). This is why recent trade deals with those countries have agricultural biotechnology provisions that seek to eliminate overreactions to low-level presence events as well as

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191 *See* Stéphan Marette et al., *"A Comparison of EU and US Consumers' Willingness to Pay for Gene-Edited Food: Evidence from Apples*. 159 APPETITE 1, 10, (2021); Stéphan Marette et al., *Can Foods Produced with New Plant Engineering Techniques Succeed in the Marketplace? A Case Study of Apples*, 45 APPLIED ECON. PERSPS. & POL'Y 414, 430 (2023).

192 Council Directive 90/220, art. 2, para. 2, 2001 O.J. (L 106).

193 *See* European Commission, *Questions and Answers on the Regulation of GMOs in the EU*, April 30, 2004 (discussing EU Regulation 1829/2003, EU Regulation 1830/2003 & EU Regulation 641/2004), available at https://ec.europa.eu/commission/presscorner/detail/en/MEMO_04_102.

194 *See* 2023 NATIONAL TRADE ESTIMATES REPORT, *supra* note 176, at 160.

195 *See id.*

196 *See id.*

197 OFF. OF THE U.S. TRADE REPRESENTATIVE, OFF. OF THE PRESIDENT, 2020 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 187 (2020) [hereinafter 2020 NATIONAL TRADE ESTIMATE REPORT].

seeking more transparency and avoiding undue delay in the approval process.

EU regulatory hostility to gene-edited foods is now on par with that towards GMO foods, although the science community in Europe has reacted quite negatively to this development caused by a 2018 European Court of Justice ruling.[198] This stands in sharp contrast to European scientific community's relative silence in reaction to Europe's original GM regulation decades ago. The European Court of Justice (ECJ) issued a ruling in July 2018 holding that products obtained by gene-edited techniques (also referred to as directed mutagenesis) were considered genetically modified organisms (GMOs) within the meaning of the E.U.'s relevant directives and regulations and thus would be regulated as GMOs, including a requirement to affix a GMO label to such products.[199] The ECJ's analysis found that the exemption of mutagenesis in the relevant directive "applies only to organisms obtained through the techniques of mutagenesis which have long been used in the conventional breeding and were deemed by the Directive to have a long safety record—which may, however, be the subject of national legislation."[200] The applicants in the case, Confédération Paysanne, a French agricultural union defending the interests of small-scale farmers, and eight other associations, argued that "only those mutagenesis techniques that were used as a matter of routine at the time of the adoption of the GMO Directive fall under the mutagenesis exemption, namely, *in vivo* random mutagenesis, as opposed to any other techniques, whether it is random *in vitro* or, a fortiori, directed mutagenesis [gene editing]."[201] The British and Greek governments argued that no

198 *See* Press Release, John Innes Ctr., European Science Community Urges Rethink on Gene Editing (July 25, 2019), https://www.jic.ac.uk/press-release/european-science-community-urges-rethink-on-genome-editing/ [https://perma.cc/3QNF-J23S] (noting statement signed by 126 scientific organizations).

199 *See* Case C-528/16, Confédération Paysanne v. Premier Ministre, ECLI:EU:C:2018:583, ¶¶ 38, 82 (July 25, 2018), https://curia.europa.eu/juris/document/document.jsf;jsessionid=FF8398D05500EA71016E0DC9A47F42BD?text=&docid=204387&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=154043 [https://perma.cc/WJB2-3LYB].

200 *See* Gelinsky & Hilbeck, *supra* note 27, at X.

201 *See* Case C-528/16, Confédération Paysanne v. Premier Ministre, ECLI:EU:C:2018:20, ¶¶ 24, 70 (Jan. 18, 2018), http://curia.europa.eu/juris/document/document.jsf?text=&docid=198532&pageIndex=0

distinction should be made between mutagenesis techniques, but the French and Dutch governments argued all new techniques should be subject to safety review in line with the precautionary principle.[202] The ECJ ruled that the E.U.'s GMO directive "cannot be interpreted as excluding, from the scope of the directive, organisms obtained by means of new techniques/methods of mutagenesis which have appeared or have been mostly developed since the directive was adopted" in 2001.[203] Accordingly, the ECJ held that the directive must be interpreted as meaning that organisms obtained by means of directed mutagenesis, such as gene editing, constitute GMOs within the meaning of the directive.[204] Because the ECJ found that gene-edited technologies were covered by the directive, they did not find it necessary to rule on an additional argument that failure of the directive to cover gene-editing technologies would be invalid because it would ignore the precautionary principle as guaranteed in the Treaty on the Functioning of the European Union Article 191(2).[205]

The United States raised its concerns in the WTO SPS Committee that the ECJ "ruling would lead to unjustified barriers to trade in products of genome editing, as well as stifle the agricultural research and innovation necessary to prevent hunger and malnutrition in the coming decades, while ensuring environmental sustainability of agricultural activities."[206] The United States also called on the E.U. to "provide the scientific basis for the regulatory distinctions made across the products of mutagenesis, whereby

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&doclang=en&mode=lst&dir=&occ=first&part=1&cid=5688996 [https://perma.cc/P62R-GNU3] (describing the parties of the case and their respective arguments).

202 *See id.* at ¶¶ 71, 74 (describing the parties of the case and their respective arguments).

203 *See* Case C-528/16, Confédération Paysanne v. Premier Ministre, ECLI:EU:C:2018:583, ¶ 51 (July 25, 2018), https://curia.europa.eu/juris/document/document.jsf;jsessionid=FF8398D05500EA71016E0DC9A47F42BD?text=&docid=204387&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=154043 [https://perma.cc/WJB2-3LYB].

204 *See id*. ¶ 54.

205 *See id*. ¶¶ 83–85.

206 Comm. on Sanitary and Phytosanitary Measures, *Note by the Secretariat: Summary of the Meeting of 1-2 Nov. 2018*, WTO Doc. G/SPS/R/93 at ¶ 3.20 (Nov. 2, 2019), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/G/SPS/R93.pdf&Open=True [https://perma.cc/NQD9-YJEK]

products of random mutations induced by chemicals or radiation were exempted from any regulatory review, and products with precise mutations induced through biotechnology were subject to protracted premarket regulatory review."[207]

The crux of the U.S. concern is that the ECJ ruling subjects products of directed mutagenesis (e.g. gene editing) to the provisions of the GM release directive and thus implies that randomly induced mutagenesis and directed mutagenesis (e.g. gene editing) are sufficiently distinct to warrant differential treatment under the release directive.[208] Additionally, the Court of Justice ruling also does not take into account that many products of directed mutagenesis (e.g. gene editing) would be indistinguishable from those from natural, spontaneous processes.[209]

But it is not only trading partners that are raising concerns with the E.U. approach to gene-edited food. The European Academies of Science Advisory Council (EASAC) has determined that current E.U. regulations are "no longer fit for purpose" and is demanding a "radical reform of the legal framework."[210] Subsequently, in January 2020, more than twenty-five European business organizations sent a letter to the E.U. Commission and Member States claiming that gene-edited crops and food should not be subject to the 2001/18 Directive if they "could also have been obtained through conventional methods or result from spontaneous processes in nature." The E.U. Council, hearing the concerns of scientist and companies, called for a Commission study and welcomed a Commission proposal that will ease rules connected with gene-edited crops and foods.[211] The Commission proceeded with a proposal that will relax rules related to gene editing in July

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207 *Id*.

208 *See id*.

209 *See id*.

210 *See* Joan Conrow, *Top European Science Council Demands Radical GMO Regulatory Reform,* ALL. FOR SCI. (Mar. 5, 2020), https://allianceforscience.cornell.edu/blog/2020/03/top-european-science-council-demands-radical-gmo-regulatory-reform/ [https://perma.cc/Z6PL-RTHC].

222 *See 26 Business Organizations Support a Commission sSudy on "Novel Genomic Techniques" and Express Their Hope for More Enabling Regulations*, EUROSEEDS (Jan. 13, 2020), https://www.euroseeds.eu/news/update-26-european-business-organisations-ask-the-eu-to-submit-a-study-on-the-status-of-novel-genomic-techniques/ [https://perma.cc/5AZ5-F368].

2023.[212] However, the proposal needs the approval of the European Parliament and the European Council, and while many E.U. countries are supportive, some may resist.[213]

Companies both within and outside of Europe are understandably concerned with the Court of Justice ruling.[214] Bayer (recent purchaser of Monsanto) and Syngenta issued negative reactions to the ruling stating it would mean that gene-edited products could not be developed for the European market.[215] BASF was one of the lone companies that believes they will not be impacted much by the ruling but even they expressed worry over European consumer impact.[216]

B. The Modern Approach of Gene-Editing Leaders: Argentina & the United States

1. Argentina

Argentina issued the world's first regulation dealing with new plant breeding technologies, such as gene editing, in 2015

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212 *See Commission Proposal on Plants Obtained from Certain New Genomic Techniques*, EURO. COMM'N: FOOD SAFETY (July 5, 2023), https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en [https://perma.cc/YUU4-EG5X].

213 *See, e.g.*, Goda Naujokaitytė, *Comm'n Proposes Revamp to Restrictive EU Genetic Engineering Rules*, SCIENCE|BUSINESS, (July 6, 2023), https://sciencebusiness.net/news/agrifood/commission-proposes-revamp-restrictive-eu-genetic-engineering-rules [https://perma.cc/J2P6-4MBW] (Germany backs changes to EU's gene editing legislation but the Greens in the European Parliament are likely to oppose); Chiara Swaton & Julia Dahm, *Ger. Austria in United Front Against Brussels' Gene-Editing Plans*, EURACTIV (July 12, 2023), https://www.euractiv.com/section/agriculture-food/news/germany-austria-a-united-front-against-brussels-gene-editting-plans/ [https://perma.cc/LXC4-XW3D] ("[A]griculture ministers of Germany and Austria oppose plans to deregulate new genetic techniques EU-wide . . . only the Greens have opposed the proposal, speaking out against the deregulation[.]").

214 *See, e.g.*, Sarantis Michalopoulos, *Industry Shocked by EU Court Decision to Put Gene-Editing Technique Under GM Law*, EURACTIV (July 25, 2018), https://www.euractiv.com/section/agriculture-food/news/industry-shocked-by-eu-court-decision-to-put-gene-editing-technique-under-gm-law/ [https://perma.cc/XG6A-EDVG].

215 *See Bayer, BASF to Pursue Gene-Editing Elsewhere After EU Ruling*, REUTERS (July 27, 2018), https://www.reuters.com/article/uk-eu-court-gmo-companies-idUKKBN1KH1PL [https://perma.cc/2VZ7-GVZE].

216 *See id.*

(Resolution no.173/2015).[217] Importantly, the Argentina regulation makes clear that products that do not contain foreign DNA (i.e. are without a transgene) do not fall under the regulation.[218] It appears that the Argentine regulation is only concerned with whether the foreign DNA is present in the final product or not.[219] And, of course, if no DNA vector is used in the process (e.g. if a ribonucleoprotein is used instead), the Argentina regulation would also not apply.[220] The Biosafety Committee receives a dossier from an applicant to start the process and the committee will then evaluate if there "is a new combination of genetic material in the genome."[221] Thus, the following determinations are possible:

> In affirmative cases, the product is considered a GMO and the applicant is notified that the product will be subject to the corresponding regulatory procedures. In negative cases, the committee analyses if the development of the [novel

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217 *See generally* Resolution 173/2015, Secretary of Agriculture, Livestock & Fishing, B.O. (May 18, 2015), https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-173-2015-246978/texto [https://perma.cc/DD7V-MEKC].

218 *See* USDA Foreign Agric. Serv., *Agricultural Biotechnology Annual.* at 17 (Feb. 2, 2019) ("Resolution no. 173/15 of the Secretariat of Agriculture, Livestock and Fisheries (attached as an Appendix) established procedures to determine the criteria under which a crop obtained by breeding techniques involving modern biotechnology does not fall under 'GMO' regulation. To this end, applicants submit each product (NBT-derived crop) to establish whether the result of the breeding process is a new combination of genetic material or not. A genetic change is regarded as a new combination of genetic material when a stable and joint insertion of one or more genes or DNA sequences that are a part of a defined genetic construct are introduced permanently into the plant genome. Also, if appropriate, the existence of sufficient scientific evidence must support the absence of transgenes that may have been used transiently during the crop breeding process."), https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename?filename=Agricultural%20Biotechnology%20Annual_Buenos%20Aires_Argentina_2-15-2019.pdf [https://perma.cc/6FFL-NM4G].

219 Ishii & Araki, *supra* note 179 ("[Most] plant genome editing experiments use Agrobacterium-mediated transformation to deliver genome editing nucleases into plant cells. In such cases, the Ti plasmid that is used can be incorporated in the plant genome, which may be interpreted as a transgene even under product-based GMO regulations. Indeed, recent plant research demonstrated the genomic insertion of plasmid-derived DNA sequences by transfecting Arabidopsis protoplasts with Cas9 and gRNA plasmids.").

220 *See id.* ("[T]he deregulation would be more likely if researchers use CRISPR/Cas9 in the form of a ribonucleoproein which can be delivered into plant cells without the use of a DNA vector." (citing Wood et al., 2015)).

221 Dennis Eriksson et al., *A Comparison of the EU Regulatory. Approach to Directed Mutagenesis with that of Other Jurisdictions, Consequences for Int'l Trade & Potential Steps Forward*, 222 NEW PHYTOLOGIST 1673, 1675 (2019).

> biotechnology] product uses a transgene temporally. If it does, and the final product is not free of transgene, it is considered GM. If the product does not contain a new combination of genetic material in the genome generated by the use of these techniques, the applicant will be notified that the product does not fall under the GMO Resolution and the plants will be treated as conventionally bred varieties.[222]

Some studies indicate that Argentina's ground-breaking regulatory approach is "already stimulating local innovation processes," with an increase in new technology developers and among a more diverse set of products—confirming some predictions that gene editing will be a "democratizing technique." The Argentine regulation inspired similar regulations to be adopted throughout much of South America.[223]

2. United States of America

Starting in roughly 2015, the USDA took numerous actions under prior regulations essentially declaring that gene-edited crops were not subject to regulations because they did not involve or create plant pests.[224] Then, on May 14, 2020, the USDA issued a new rule that essentially codifies and further liberalizes the importation, interstate transport, and environmental release of gene-edited crops by USDA.[225] As stated by the USDA, "This final rule, which marks the first comprehensive revision of the regulations since they were established in 1987, provides a clear, predictable, and efficient regulatory pathway for innovators, facilitating the development of genetically engineered organisms that are unlikely to pose plant pest risks."[226] The new regulation is true product-based regulation, namely USDA-APHIS will "focus entirely on new traits themselves rather than the method or technology in which the crop

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222 *Id*.

223 *See* Whelan et al., *supra* note 43, at 7.

224 *See* Letter from USDA to Professor Yang (Apr. 13, 2016), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/15-321-01_air_response_signed.pdf [https://perma.cc/6DP6-8EEQ]; *see also* Press Release, USDA, Secretary Purdue Issues USDA Statement on Plant Breeding Technologies (Mar. 28, 2018), https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation [https://perma.cc/7HTH-L3U4].

225 *See* Final Rule on Movement of Certain Genetically Engineered Organism, 7 C.F.R. §§ 330, 340, 372 (hereinafter Final Rule on Movement).

226 *Id.*

is created."[227] USDA-APHIS regulatory authority is based on whether a product is a plant pest or poses a risk of being one.[228] If an article is considered a "regulated article" on this basis, the USDA has authority to control the import, handling, interstate movement and release into the environment.[229]

Several reviews by National Academy of Sciences found that gene-editing methods do not raise risks beyond conventional methods of breeding.[230] Under the new rules, a gene-edited plant will not be "regulated if it contains minor changes—a change to a pair of amino acid bases or a deletion of a chunk of DNA—that would create a trait that could have been made through traditional breeding."[231] Thus, gene-editing companies can without regulation cut disease resistance genes from various parts of a plant's genome and subsequently place them into one stretch of DNA, allowing breeders to easily incorporate all these genes into one variety—something that saves incredible time and effort from conventional methods. The only seeming frustration left among gene-editing producers is "that the exemption doesn't cover more substantive changes or moving genes between closely related plants, such as peppers and tomatoes, which can't be crossed with conventional breeding."[232] However, the end result of the regulation is that most

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227 *Id.*

228 *See* Neil E. Hoffman, *Revisions to USDA Biotechnology Regulations: The SECURE rule*, 118 PNAS, no. 22, Apr. 30, 2021, at 1, 4.

229 *Id.* at 5.

230 *See, e.g.*, NAT'L ACAD. OF SCI'S., REPORT IN BRIEF OF GENETICALLY ENGINEERED CROPS: EXPERIENCES & PROSPECTS (May 2016), https://nap.nationalacademies.org/resource/23395/GE-crops-report-brief.pdf [https://perma.cc/WBS9-3XQQ].

231 *See* Erik Strokstad, *United States Relaxes Rules for Biotech Crops*, SCI. MAG. (May 18, 2020), https://www.science.org/content/article/united-states-relaxes-rules-biotech-crops [https://perma.cc/9XDT-U4J8]; see also *Questions & Answers: Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) Rule*, USDA.GOV (June 2020), https://www.aphis.usda.gov/biotechnology/340-secure-rule-qa.pdf [https://perma.cc/7VAT-T7ES] (stating the regulation "exempts from regulation plants that could otherwise have been developed through conventional breeding techniques. Examples of genetic changes exempt from regulation include gene deletions and simple genetic transfers from one compatible plant relative to another . . . . Although plants developed using genome editing techniques are exempt from regulation if they could have otherwise been produced through conventional breeding techniques, the regulations focus on the plant pest risk presented by the product. Thus, some plants developed using genome editing techniques will be regulated if they pose a plausible plant pest risk.").

232 *See* Stokstad, *supra* note 231.

gene-edited plants will escape regulation and, to the chagrin of many environmental and consumer NGOs and even some biotech developers and food industry representatives, developers do not even have to notify USDA if they believe they are unregulated.[233]

The new regulation is largely a codification of the Secretary of Agriculture's March 2018 statement that "USDA does not regulate or have plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or developed using plant pests."[234] The Secretary's statement specifically indicated that gene-edited crops fell outside of USDA's regulation. Indeed, in the decade prior to the new 2020 regulation, numerous plant species were authorized by the United States.[235] USDA's response to at least six regulatory inquiries by private and public developers was that soybean, rice, wheat, white button mushroom and maize—modified via NHEJ using TALENs or CRISPR/Cas9 for better nutrient composition or disease resistance or avoidance of color deterioration—did not constitute a non-plant pest or noxious weed and thus were "unregulated" and could be tested in fields without USDA oversight.[236]

Of course, within the U.S. system, the FDA and EPA also have a regulatory role to play in gene-edited food and crops, respectively. These agencies' role has been described as follows: "FDA has primary responsibility for ensuring the safety of human food and animal feed, as well as proper labeling and safety of all plant-derived foods and feeds. EPA regulates pesticides, including plants with plant-incorporated protectants (pesticides intended to be produced and used in a living plant), to ensure public safety."[237] There is significant coordination among the three agencies.

Inspired by a September 2020 Biden Administration Executive

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233 *See Trump Administration's USDA Limits Oversight of Genetically Engineered & Gene Edited Crops*, CTR. FOR SCI. IN THE PUB. INT. (May 14, 2020), https://www.cspinet.org/press-release/trump-administrations-usda-limits-oversight-genetically-engineered-and-gene-edited [https://perma.cc/MY6R-9VMH].

234 *See* Press Release, Sonny Perdue, Secretary, U.S. Dep't of Agric., Statement on Plant Breeding Innovation (Mar. 28, 2018), https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation [https://perma.cc/A45Y-85UX].

235 *See* Garcia Ruiz, *supra* note 3, at 153–54.

236 *See id.*

237 *See* Hoffman, *supra* note 228, at 4.

Order, EPA issued new regulations on May 31, 2023 concerning gene-edited products.[238] Under the new rule, a class of plant-incorporated protectants (PIP) created using genetic engineering are exempted from registration requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and from the food or feed residue tolerance requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA).[239] The logic of the new rule is to exempt PIPs where they pose no greater risk than already approved ones and where they could have been created using traditional breeding techniques (with gene editing simply speeding up their creation).[240] This is a change in attitude by EPA that several years earlier indicated that the 'the degree of editing . . . does not necessarily influence the pesticidal nature of the product' and that 'knockouts could still be considered as plant-incorporated protectants depending on the . . . intent of the product such as disease resistance."[241]

The FDA has not issued new regulations; rather FDA is using the same voluntary consultation method it uses for GM foods and feed. Currently, food producers are not required to identify whether some or all of the ingredients derive from GMOs. The practice stems from the FDA's 1992 policy statement,[242] in which the FDA considered most GMO crops 'substantially equivalent' to non-GMO crops; in such cases, GMO crops would be designated as 'Generally Recognized as Safe' (GRAS) under the Federal Food, Drug, and Cosmetic Act and would not require pre-market approval. Today, the FDA does not have a mandatory GM or gene-edited food safety assessment process. Instead, the FDA continues to operate a voluntary program for pre-market review of GM and gene-edited foods, although all prior GM and future gene-edited food crops

238 *See* Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies, 88 Fed. Reg. 34756 (May 31, 2023) (to be codified at 40 C.F.R. pt. 174).

239 *See id.*

240 *See id*. ("Due to the sophistication of these technologies, PIPs can now be created through genetic engineering that are virtually indistinguishable from those created through conventional breeding. These advances also allowed EPA to develop specific exemption criteria to circumscribe PIPs created through genetic engineering that pose no greater risk than the PIPs created through conventional breeding that have been exempt since 2001.")

241 *See* Eriksson et al., *supra* note 221, at 1678.

242 *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992).

commercialized go through this voluntary review process.[243]

C. The Americas

Argentina's regulatory lead has been followed by eight other Latin American countries in the past seven years.[244] In North America, Canada has a regime distinct from the United States, but it is implemented in a manner generally friendly to gene-edited crops and food. Canada's regulatory system is generally influenced by the liberal approach to gene-edited crops and food taken by the United States.[245] USMCA provisions on biotechnology will create further incentives for harmonization in results under, if not the detailed designs, of, each countries' regulatory system.

All GM varieties in Canada have been treated as "novel technologies" since 1995.[246] Until just recently, under Canada's regulatory system "if the technology creates a novel product, then Canada's PNT [plants with novel traits] regulations are triggered, resulting in additional regulatory oversight on allergenicity, toxicity and impacts on non-target organisms."[247] Any plant type subject to PNT regulations will require Canadian Food Inspection Agency and Health Canada approval for "unconfined release status."[248] Novel is not defined formally in Canada's regulations. However, Canadian agricultural biotechnology breeders "use[d] a rule of thumb that if the specific trait they are selecting for expresses at 20% to 30% higher or lower than conventional varieties, the plant breeder initiates discussions with regulators regarding the applicability of PNT regulations in the specific instance."[249] Until recently,

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243 *See How GMOs Are Regulated in the U.S.*, FDA.GOV (Apr. 19, 2023), https://www.fda.gov/food/agricultural-biotechnology/how-gmos-are-regulated-united-states [https://perma.cc/QZB4-REQH].

244 *See* Whelan et al., *supra* note 43, at 7. ("[T]he forerunner Argentine regulation has inspired another eight countries in Latin America to enact similar regulations in less than 4 year[s.]").

245 *See* Stuart J. Smyth, *Canadian Regulatory Perspectives on Genome Engineered Crops*, 8 GM CROPS & FOOD 35, 42 (2017) ("Canada's approval of NBT products demonstrates that regulatory harmonization with the United States is important and that Canada's regulatory decision-making process delivers risk assessment decisions that are consistent with the USA. In the case of GM apples, Canada's approval followed that of US regulators by a few months.").

246 *See* Eriksson, *supra* note 221, at 1676-77.

247 *See* Smyth, *supra* note 245, at 38.

248 *See id.*

249 *See id.*

Canada's PNT regulations "appl[ied] to all plant varieties having a novel trait, regardless of how they were developed," meaning that the variety could be developed by gene editing, genetic modification, mutagenesis or even conventional breeding.[250] In implementation, the Canadian system was not nearly as restrictive as many other countries around the globe.[251] However, in May 2023, Canada's Food Inspection Agency announced a major change regarding gene-edited plant varieties. A variety developed with gene editing will not require additional assessment so long as the resulting plants do not contain DNA from another species.[252] As regards food products, Health Canada's updated July 2022 guidance makes clear only those foods that contain foreign DNA would need to go through pre-market notification and assessment as novel foods.[253]

Mexico's regulatory environment for GM and gene-edited crops and food has not been nearly as favorable. Despite being required by Mexico's biosafety law to make decisions on applications within six months, Mexico's Agricultural Biotechnology COFEPRIS has not made any decisions on applications for authorization of agricultural biotechnology products intended for use in food and feed since May 2018.[254] This is part of the motivation for the procedural and timing of agriculture biotechnology provisions

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250 *See id.*

251 *Compare supra* notes 246–50 and accompanying text with discussion of European approach, *supra* notes 189-204 and accompanying text, and analysis of other countries *infra* in text.

252 *See Directive 2009-09: Plants with Novel Traits Regulated under Part V of the Seeds Regulations: Guidelines for Determining when to Notify the CFIA*, CANADA FOOD INSPECTION AGENCY, § 4.5 (May 3, 2023), https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/eng/1304466419931/1304466812439 [https://perma.cc/8HDC-JUET].

253 *See Guidelines for the Safety Assessment of Novel Foods*, HEALTH CANADA, § 4.4 (July 2022), https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidelines-safety-assessment-novel-foods-derived-plants-microorganisms/guidelines-safety-assessment-novel-foods-2006.html [https://perma.cc/VWT2-4K2Z] ("Of specific importance for gene-edited plants, the DNA encoding gene editing machinery (e.g., CRISPR Cas protein(s) and associated guide RNAs) is considered to be foreign DNA if present in the final product. Most plant developers will remove this DNA through subsequent plant breeding; however, in the event that a gene-edited plant still contains the DNA encoding this machinery within its genome, foods derived from such a gene-edited plant require pre-market notification and assessment as novel foods.").

254 *See* 2020 NATIONAL TRADE ESTIMATE REPORT, *supra* note 197, at 346.

within the USMCA. Despite biotech cotton being grown in Mexico for well over two-decades, Mexico has recently rejected an application for biotech cotton.[255] This is one of the reasons that the USMCA reemphasizes the need for a science- and risk-based approach. More recently, Mexico's President has issued a decree that would ban GM corn for human consumption, although details of the ban have been modified somewhat.[256] In March 2023, the United States requested technical consultations under the USMCA regarding the ban and ultimately filed a formal dispute settlement case in June 2023.[257]

CTNBio is the major regulatory body in Brazil. Under Brazil's system,[258] products created through gene editing are subject to a "case-by-case consultation system" to see if the product "will be considered a conventional or a transgenic organism."[259] In most situations, products meeting the following criteria will be considered as conventional products: "the absence of recombinant DNA/RNA in the progeny, the presence of genetic elements that could be obtained by conventional breeding; the presence of induced mutations that could also be obtained by older techniques, such as radiation or chemical mutagenesis, or even the presence of induced mutations that could occur naturally."[260] Numerous gene-edited products have been approved to be conventional products under Brazil's system.[261] Chile's regulatory scheme focuses on whether a "new combination" of genetic material is present in the product, and a "new combination" appears to require foreign DNA

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255 *See id.* at 346.

256 *See* Cassandra Garrison, *Mexico to fight US dispute over GM corn after formal consultations fail,* REUTERS (June 2, 2023), https://www.reuters.com/markets/commodities/us-requests-dispute-settlement-consultations-with-mexico-over-gm-corn-2023-06-02/ [https://perma.cc/2FWB-9D2W].

257 *See US Asks Mexico for Trade Consultations over GM Corn Limits*, ASSOC'D. PRESS (March 6, 2023), https://apnews.com/article/us-mexico-corn-trade-ban-genetically-modified-e391801aec39fe442b12ea7ed47a8190 [https://perma.cc/7APB-ADKY]; Garrison, *supra* note 254.

258 *See generally* Nat'l Biosafety Technical Comm'n Res. 16 (15 Jan. 2018).

259 Eriksson et al., *supra* note 221, at 1676.

260 Paulo P. Andrade, et al., *GM Insect Pests Under the Brazilian Regulatory Framework: Development and Perspectives*, 12 BMC PROCEEDINGS (SUPPLEMENT 8) 13, 16 (2016).

261 *See id.*

be present in the final product.[262] Columbia has also established a procedure to determine whether products that contain no foreign DNA should be treated as GM.[263] Bolivia also shows signs of joining in a more liberal approach to gene editing through new regulations.[264]

Despite the overall positive treatment of gene-edited crops and food within the Americas, there are still countries with a negative environment for such crops and food. Peru has a ban on the importation of biotech seeds and food products that has been in place for nearly a decade.[265] The ban was instituted three years after conclusion of the FTA between the Peru and the United States[266]—an FTA which did not contain any specific provisions on agricultural biotechnology.[267] To make matters worse, "on January 6, 2021, the Peruvian congress passed Law No. 31111, which extended Peru's moratorium on the cultivation and import for cultivation of genetically engineered organisms, such as seeds, for fifteen years."[268] Despite regular discussions between Peru and the United States in the context of the SPS committee under the FTA, Peru has not made any changes to date.[269]

D. Asia

Asian governments employ a range of regulations on gene-edited crops and food. Japan is quite open to gene-edited foods. Japan's Consumer Affairs Agency ruled in December 2019 that gene-edited foods do not have to undergo safety inspections (such as checking toxicity and carcinogenicity) that are applied to GM foods on the condition that no foreign DNA remains in the final product.[270] Further, such products need not be notified to the

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262 Eriksson et al., *supra* note 221, at 1677.

263 *See id.*

264 *See* 2020 NATIONAL TRADE ESTIMATE REPORT, *supra* note 197.

265 *See Ten Year Ban on Genetically Modified Seeds and Foods Takes Force Thursday,* ANDEAN AIR MAIL & PERUVIAN TIMES, (Nov. 17, 2012), https://www.peruviantimes.com/17/ten-year-ban-on-genetically-modified-seeds-and-foods-takes-force-thursday/17479/ [https://perma.cc/DR5K-QQJR].

266 *See* Peru Trade Promotion Agreement, Peru-U.S. Apr. 12, 2006,

267 *See id.* (lacking any provisions on agricultural biotechnology).

268 *See* 2023 NATIONAL TRADE ESTIMATE REPORT, *supra* note 176 at 326.

269 *See id.*

270 *See* Guan Yu Lim, *Genome-Edited Products to Go on Sale in Japan, Despite No*

government nor labelled.[271] Japan already has numerous gene-edited products on their commercial market, including tomatoes.[272]

The Chinese government formally approved a 5-year plan for developing gene editing of plants in 2016, and its purchase of Syngenta only further highlights China will pursue in a very significant way gene-editing technology.[273] However, China has not announced a policy on gene-edited foods nor a direct regulatory approach. China's regulatory treatment of GM food and crops has caused much concern as described above, and is the reason agricultural biotechnology provisions were negotiated in the Phase I Deal with China. In essence, China is trying to catch up technologically on bioengineered agriculture and does not want its market opened up yet.

Most other countries in Asia have not announced formal policies or regulatory approaches to gene-edited crops and food. However, while treatment of GM crops and food is reason for significant concern in most countries, there are also very recent developments in several large markets indicating that gene-edited products will receive improved regulatory treatment. South Korea's biotech review process is very slow and inefficient involving redundant reviews and data requests by five different agencies—and this process is enshrined in law so would take legislative change to fix.[274] Yet, there is a 2022 proposal in the Korean legislature to exempt gene-edited products from full review, even though gene-edited products would be defined as LMOs.[275] Similarly, the Philippines had a five agency approval process as a result of a 2015 Philippine Supreme Court decision.[276] However, in 2022, the

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Labeling and Safety Provisions, FOOD NAVIGATOR ASIA (Dec. 5, 2019), https://www.foodnavigator-asia.com/Article/2019/12/05/Genome-edited-food-products-to-go-on-sale-in-Japan-despite-no-labelling-and-safety-provisions [https://perma.cc/BVT5-39JU]; *see also* Eriksson et. al., supra note 219, at 1679.

271 *See generally* Kazunari Kondo & Chie Taguchi, *Japanese Regulatory Framework and Approach for Genome-Edited Foods Based on Latest Scientific Findings*, 10 FOOD SAFETY (TOKYO), no. 4, Dec. 2022, at 113–28.

272 *See id.*; *see also* Dennis Normile, *Gene-Edited Foods are Safe, Japanese Panel Concludes*, SCI. MAG. (Mar. 19, 2019), https://www.science.org/content/article/gene-edited-foods-are-safe-japanese-panel-concludes [https://perma.cc/TUH7-EX8L].

273 *See* Cohen*, supra* note 53.

274 *See* 2023 NATIONAL TRADE ESTIMATE REPORT, *supra* note 176, at 257.

275 *See id*.

276 *See* 2020 NATIONAL TRADE ESTIMATES REPORT, *supra* note 197, at 402.

Philippines streamlined the review process for agriculture biotechnology products.[277] Malaysia has very steadily approved the use of agriculture biotechnology products and by the end of 2022 had "approved 57 [agriculture biotech] products for market release for use in food, feed, and processing."[278] Burma drafted a framework for biotech products over a decade ago, but never finalized it, and is currently redrafting that framework in light of gene-editing developments. It appears there is no law in Burma prohibiting import of GM (or gene-edited) crops or food, although some government officials indicate there may be a de facto ban in place.[279] Taiwan has at least three measures in place that inhibit or could inhibit trade in GM foods: 1) a ban on use in school meals; 2) separate Harmonized System Codes for such imports from their conventional analogues; and 3) a traceability and 5-year record keeping requirement for imports.[280] Thailand prohibits cultivation of GM crops but allows imports of processed foods with such ingredients and a number of GM products, but the United States is concerned that regulations that went into effect at the end of 2022 could "delay or disrupt the importation of all processed foods containing [agriculture biotech] organisms or products and ingredients derived from them (including plants, animals or microorganism) into Thailand."[281] Vietnam allows the importation of many GM products but it's approval process is still characterized as inconsistent and unpredictable.[282] Similarly, India's GM regulatory regime is described as "slow, opaque, subject to political influences."[283] With many of the countries discussed above involved in the IPEF negotiations, there is an opportunity to push forward positive reform of gene-edited crops and food regulation within the agreement.

E. Africa

African countries face subtle but persistent pressure from the E.U. to follow its regulatory model on GM and gene-edited crops

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277 *See* 2023 NATIONAL TRADE ESTIMATE REPORT, *supra* note 176, at 332.

278 *See id*. at 275.

279 *See generally,* 2020 NATIONAL TRADE ESTIMATES REPORT*, supra* note 197.

280 *See id.*

281 *See* 2023 NATIONAL TRADE ESTIMATES REPOrt, *supra* note 176, at 389.

282 *See id*. at 434.

283 *See id.* at 202.

and foods. Numerous African countries prohibit imports of either GM/gene-edited seeds (with some exceptions for research purposes) or all GM/gene-edited grains and foods (with the exception of food aid).[284] Kenya appears to be the most forward leaning country on gene editing and is already experimenting with gene-edited products. Kenya originally instituted a ban on marketing and import of GM food and feed in 2012.[285] However, on October 3, 2022, Kenya lifted this ban on the import and commercialization of genetically engineered products, opening a path to cultivation and import of GM food and feed.[286] In 2023, litigation contesting the end of the ban has held up the removal of the ban but the expectation is that it will be removed eventually.[287] Kenya is the first country on the continent to draft new regulations governing gene-edited crops providing for case-by-case review, although Nigeria, the largest economy on the continent, has recently provided for case-by-case review as well.[288] Kenya's National Biosafety Authority approved two gene-editing applications for banana and yam late in 2019, albeit only for "contained use."[289] Further, Bt Cotton commercial cultivation is now allowed but "Kenya's commercialization of GE Gypsophila flower (baby's breath) intended for export to the international cut flower market, including the United States, is stalled due to concerns on its potential impact on trade with the European Union (EU)."[290] In a significant negative development, South Africa, the second largest market on the continent, actually classified gene-edited crops as GM under its existing law in 2021.[291]

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284 *See* Algeria and Angola Sections in USTR, National Trade Estimates Report 2020, *supra* note 195.

285 *See id.* at 306.

286 *See* 2023 NATIONAL TRADE ESTIMATE REPORT, *supra* note 176, at 251.

287 *See id.* at 251.

288 *Global Gene Editing Regulation Tracker, Africa: Crops/Food*, GLOBAL LITERACY PROJECT (Sept. 10, 2023), https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/africa-crops-food/ [https://perma.cc/Q9NT-QGP5].

289 *See* Verenardo Meeme, *African Scientists Urge Use of Gene Editing to Improve Crops*, ALL. FOR SCI. (Sep. 4, 2019), https://allianceforscience.org/blog/2019/09/african-scientists-urge-use-gene-editing-improve-crops/ [https://perma.cc/M6WZ-CZ5V].

290 *See* 2020 NATIONAL TRADE ESTIMATE REPORT, *supra* note 197, at 306.

291 *See Global Gene Editing Regulation Tracker, Africa: Crops/Food*, *supra* note 288.

F. Australia/New Zealand

Australia, like Canada, is a very large agricultural exporter and thus one might assume Australia would be wary of adopting overly restrictive regulations that might be mimicked abroad or lend support to restrictive regulatory regimes abroad. Australia is a very large GM producing agricultural nation, as nearly all cotton grown in Australia is GM.[292] Due to the limited number of types of GM crop and the paucity of gene-edited crops to date,[293] Australia may be less motivated to adopt and agree internationally to pro-gene-editing regulatory regimes than one might at first glance assume. Australia's approach is to adjust to export market requirements and in essence this is not yet a problem for Australia because GM cotton is so prevalent and accepted globally.

Australia's regulatory regime is based on The Gene Technology Act 2001.[294] This Act provides a working framework for research, field trials and commercial release of GMOs.[295] Australia is a federal state and its State and Territory Governments maintain some independent authority to regulate release of GMOs into the environment, and several states currently do not allow the commercial cultivation of GMO crops.[296] Australia engaged in regulatory reform efforts regarding gene-edited crops and decided to "take a middle way where SDN-2, SDN-3 and ODM applications would be regulated as GMO, but SDN-1 applications not."[297] SDN-1 is essentially a knock-out of a gene while SDN-2 and ODM involves a mutation of a gene while SDN-3 actually creates a

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292 *See* OFFICE OF THE GENE TECHNOLOGY REGULATOR, AUSTRALIA DEPT. OF HEALTH, GENETICALLY MODIFIED (GM) COTTON IN AUSTRALIA (Feb. 2021), https://www.ogtr.gov.au/resources/publications/genetically-modified-gm-cotton-australia [https://perma.cc/AP85-29X9] (indicating that over 99% of Cotton in Australia is GM).

293 *See Global Gene Editing Regulation Tracker, Australia: Crops/Food*, GLOBAL LITERACY PROJECT (last visited Sep. 10, 2023), https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/australia-crops-food/ [https://perma.cc/F3ZF-U6VK].

294 *See* Eriksson et al., *supra* note 221, at 1676.

295 *See id*.

296 *See id*.

297 *See id.*; Gene *Tech. Amend. (2019 Measures No. 1) Regul. 2019 (F2019L00573)*, AUSTRALIAN LEGAL INFORMATION INSTITUTE (last visited Sep. 27, 2023), http://www5.austlii.edu.au/au/legis/cth/num_reg_es/gta2019mn1r2019201900573487.html [https://perma.cc/FP4V-FFTN].

transgene (leaves foreign DNA).[298]

New Zealand amended its process-based GMO regulations in order to regulate any type of crop breeding by genome editing.[299] However, there is pressure in New Zealand, given it too is a large agricultural exporter,[300] to at least deregulate any final agricultural biotech product that does not contain exogenous DNA.

As regards gene-edited food products, Food Standards Australia New Zealand (FSANZ) assesses applications for approval for food derived from GMOs.[301] FSANZ is currently assessing how to handle gene-edited foods and under what circumstances they would not be treated as GMO food.[302] In December 2019, FSANZ concluded a review with the following recommendations:

> Recommendation 1: FSANZ prepare a proposal to revise and modernize the definitions in the Code to make them clearer and better able to accommodate existing and emerging genetic technologies.
>
> Recommendation 2: As part of the proposal, FSANZ give consideration to process and non-process based definitions and the need to ensure that NBT foods are regulated in a manner that is commensurate with the risk they pose.
>
> Recommendation 3: Throughout the proposal process FSANZ will ensure there is open communication and active engagement with all interested parties and also explore ways to raise awareness about GM and NBT foods.[303]

In February 2022, FSANZ launched a proposal to "revise and update the definitions in the Australia New Zealand Food Standards Code (the Code) for 'food produced using gene technology' and 'gene technology' to make them clearer and better reflect existing and emerging genetic technologies, including new breeding

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298 *See* C.C.M. van de Weil et al., *New Traits in Crops Produced by Genome Editing Techniques Based on Deletions*, 11 PLANT BIOTECH. REPS. 1, 1–2 (2017).

299 *See* Ishii & Araki, *supra* note 179, at 46.

300 *See* Nils-Gerrit Wunsch, *Leading Global Exporters of Agricultural Products in 2020,* STATISTICA (Sept. 12, 2022), https://www.statista.com/statistics/1332329/leading-countries-worldwide-by-value-of-agricultural-products-exported/ [https://perma.cc/CH9N-9EH4] (showing New Zealand ranking 19th).

301 *See Genetically Modified Foods*, FOOD STANDARDS AUSTRALIA NEW ZEALAND, https://www.foodstandards.gov.au/consumer/gmfood/pages/default.aspx [https://perma.cc/HW6K-ENMK].

302 *See id.*

303 *See id.*; *see also* FSANZ, Final Report, *supra* note 187.

techniques (NBTs)."[304] Due to COVID19, FSANZ delayed public consultations on a proposal to amend definitions in the food standards code concerning gene-edited products but reignited the consultation process in 2023, and expects a second round of public consultations to conclude in late 2023.[305]

V. Trade Agreement Entryways to Ensuring a Favorable Regulatory Environment for Gene-Edited Crops and Food

For trade negotiators, a traditional robust toolbox contains a full panoply of tools (see box below). Tools include global (or broad multilateral), regional, and bilateral legally binding agreements of various scope, buttressed by neutral third-party dispute resolution, as well as legally non-binding possibilities (such as ministerial declarations) at each of these levels.[306] As a general matter, legally binding is preferred for the greater predictability and certainty it provides.[307]

Tools within Trade Agreement Toolbox
(Note: Tools can be used bilaterally, regionally, and/or globally)
A: Comprehensive agreements with traditional market-access (tariff-cutting)
B: New-styled, broad scope agreements but without traditional market-access
C: Non-comprehensive agreement but that addresses multiple issues
D. Issue-specific mini-deal
E. Non-legally binding political commitments (of varying scope)

Progress on creating a favorable global regulatory and trading environment for gene-edited crops in the WTO alone will be

304 FOOD STANDARDS AUSTRALIA NEW ZEALAND, STAKEHOLDER SUMMARY REPORT PROPOSAL P1055 – DEFINITIONS FOR BREEDING TECHNOLOGY & NEW BREEDING TECHNIQUES, 4 (2022), https://www.foodstandards.gov.au/code/proposals/Documents/P1055%20Stakeholder%20Feedback%20Summary%20Report.pdf/ [https://perma.cc/FYM3-LFZA].

305 *See id.* at 17.

306 *See* Schaefer, *supra* note 8, at 2.

307 *See generally,* JOHN H. JACKSON, THE WORLD TRADING SYSTEM: LAW AND POLICY OF INT'L ECON. RELS. 1, 340 (MIT Press, 2d ed. 1997).

difficult—both in negotiations due to garnering consensus among 164 countries in an already fractured negotiating environment[308] and via dispute settlement since the Appellate Body is no longer functioning as a result of United States blocking the appointment of new Appellate Body members.[309] Additionally, the United States is not currently pursuing comprehensive free trade agreements that include traditional market access.[310] Until these avenues return, the United States needs to pursue bold provisions within existing regional and bilateral new-styled, non-comprehensive negotiations and should also establish pro-gene editing issue-specific deals with important countries in regions not currently engaged in negotiations with the United States. There is plenty of precedent for the United States entering issue-specific mini-deals on agricultural trade, including technical standards on agricultural goods.[311] Indeed, many of these agreements are entered into by the U.S. Executive Branch without formal, express approval by the Congress under the argument the Executive Branch has implied approval if the agreement requires no change in U.S. law and/or is based on past acquiescence from Congress to such agreements.[312] The goal in trade negotiations for the United States should be to create entryways in each continent among countries currently favorable to or at least taking a wait and see approach to gene-edited crops and

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308 *See generally* Schaefer, *supra* note 8.

309 *See* Chad Brown & Soumaya Keynes, *Why Did Trump End the WTO Appellate Body?* PETERSON INST. FOR INT'L ECON., (March 4, 2020, 11:30 AM), https://www.piie.com/blogs/trade-and-investment-policy-watch/why-did-trump-end-wtos-appellate-body-tariffs [https://perma.cc/RJ2K-8PEZ].

310 Ana Swanson, *Biden's Reluctant Approach to Free Trade Draws Backlash*, N.Y. TIMES, https://www.nytimes.com/2023/04/03/us/politics/biden-free-trade.html/ [https://perma.cc/G924-CNFR] ("The administration is currently negotiating trade frameworks for the Indo-Pacific region and the Americas, and is engaging in trade talks with Taiwan, Kenya and other governments. But, to the dissatisfaction of some lawmakers in both parties, none of these agreements are expected to involve significantly opening up foreign markets by lowering tariffs, as more traditional trade deals have done.").

311 *See* Kathleen Claussen, *Trade's Mini-Deals,* 62 VA. J. INT'L L. 315, 339 (2022) (noting food safety trade executive agreements constitute 12% of all such mini-deals and agriculture covers another 8%).

312 *See generally,* Kathleen Claussen & Tim Meyer, *The President's (and USTR's) Trade Agreement Authority: From Fisheries to IPEF,* INT'L ECON. L. & POL'Y BLOG (July 15, 2022, 6:58 AM), https://ielp.worldtradelaw.net/2022/07/the-presidents-and-ustrs-trade-agreement-authority-from-fisheries-to-ipef-.html [https://perma.cc/7B3X-5YFU] (noting that USTR's organic statute is argued by USTR to provide Congressional approval).

food, and then eventually create enough momentum to overcome barriers in countries with negativity towards gene editing.

A. Selecting Entryways for Gene-Edited Crops and Food in Every Region of the World

The United States is engaged in new-style, non-comprehensive negotiations in the Americas,[313] a region generally favorable to gene-edited crops and food, and the Indo-Pacific[314] where countries take a more mixed approach. It also has new-style negotiations underway with Kenya,[315] an important market in Africa, and Taiwan[316] that can be important. In picking additional bilateral partners for issue-specific pro-gene-editing provisions in each region, the United States should be guided by the size and importance and influence of the foreign market, leverage of the United States in potential negotiations and the existence of any ongoing or soon to be launched negotiations, the science community's and consumers' attitudes toward gene editing, the presence of any ongoing research projects in the foreign market, and the prospects of the country complying with any agreement reached.

Under these criteria, the U.S. government must negotiate pro-gene-editing provisions with the U.K. and possibly also with Norway and/or Switzerland in Europe. As regards the UK, interestingly, a large (but by no means unanimous) group of politicians, scientists and companies called on the U.K. post-Brexit to change gene-editing regulations and not keep the approach it was

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313 *See* U.S. DEPT. OF STATE, AMERICAS PARTNERSHIP FOR ECONOMIC PROSPERITY (2023) https://www.state.gov/americas-partnership-for-economic-prosperity/ [https://perma.cc/PZ7W-MXVW].

314 *See* Press Release, Office of the U.S. Trade Representative, US to Participate in 4th IPEF Negotiating Round in Korea (June 13, 2023), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2023/june/united-states-participate-fourth-indo-pacific-economic-framework-ipef-negotiating-round-south-korea/ [https://perma.cc/5YEZ-334K].

315 *See* OFF. OF THE U.S. TRADE REPRESENTATIVE, US-KENYA STRATEGIC TRADE AND INVESTMENT PARTNERSHIP—SUMMARY OF TEXTS PROPOSED BY THE U.S. SIDE 1 (2023), https://ustr.gov/sites/default/files/2023-05/U.S.-Kenya%20STIP%20Chapter%20Summaries%20May%202023.pdf./ [https://perma.cc/7GPZ-KCXD] ("[P]rovisions are intended to: improve transparency of regulatory processes and procedures; advance science-based decision-making to protect human, plant, and animal life and health; improve processes and promote cooperation regarding regulatory and administrative requirements; and facilitate agricultural trade.").

bound to follow as a member of the EU.[317] Their voices were heard and responded to in the Summer of 2023 when the U.K. Genetic Technology Precision Breeding Act received royal assent.[318] The Act provides for pro-gene-editing provisions for crops and does not institute a labeling requirement.[319] While it appears any move away from regulations banning chlorine washed chicken will be very politically sensitive, the post-Brexit U.K. can agree to pro-gene-editing provisions in an FTA with the United States given the complaints of a significant number of scientists and companies in the U.K. complaining of the U.K.'s "backward" approach on the issue have been heard and responded to.[320] The U.K. is the best target for an "edge of E.U." candidate for a pro-gene-editing agreement due to these developments and the size of its market.

Currently, both Norway and Switzerland have quite restrictive agricultural biotechnology regimes. Norway in essence blocks the importation of most agricultural biotechnology products, and also blocks "farmers from cultivating biotechnology crops and using biotechnology feed for farm animals."[321] However, in June 2023 Norway's Genetic Technology Committee, established in 2020 by Royal Decree, released a report warning of the risks of overly restrictive gene-editing regulation and calling for a significant easing in regulation of such products.[322] Norway is hamstrung in unilaterally changing their regime because as a European Economic

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317 *See* Johann Tasker, *Gene-Editing Vital for Future of UK Farming,* FARMERS WKLY. (May 26, 2020), https://www.fwi.co.uk/arable/gene-editing-vital-for-future-of-uk-farming [https://perma.cc/D393-VRGW]; *see also* Maria Chaplia**,** *Viewpoint: With Conservative Sweep of the 'Brexit election', Boris Johnson Poised to Steer the UK out of 'Outdated' EU GMO, CRISPR Regulations***,** GENETIC LITERACY PROJECT (Dec. 11, 2019), https://geneticliteracyproject.org/2019/12/11/viewpoint-with-conservative-sweep-of-the-brexit-election-boris-johnson-poised-to-steer-the-uk-out-of-outdated-eu-gmo-crispr-regulations/ [https://perma.cc/E47N-95TK].

318 *See* Genetic Technology (Precision Breeding) Act 2023, 2022-2023, HC Bill, Ch. 6 1,1. (UK)**.**

319 *See id.*

320 *See* Chaplia, *supra* note 317.

321 *See* 2023 NATIONAL TRADE ESTIMATE REPORT, *supra* note 176, at 304.

322 *See* Julian Little, *'More Risky to Maintain a Strict Regulation Than to Soften it': Genetic Commission in Norway Challenges EU, Urges Gene Editing Regulations Similar to Conventional Foods*, GENETIC LITERACY PROJECT, (June 13, 2023), https://geneticliteracyproject.org/2023/06/13/more-risky-to-maintain-a-strict-regulation-than-to-soften-it-genetic-commission-in-norway-challenges-eu-urges-gene-editing-regulations-similar-to-conventional-foods/ [https://perma.cc/LQ8U-YDNC].

Area (EEA) member they are bound to follow E.U. directives and regulations in the area of GMOs that have been incorporated into the EEA agreement.[323] Switzerland similarly has a very restrictive regime for agricultural biotechnology products, and even has a moratorium on planting biotech crops through 2025.[324] However, by recent enactment of the Swiss Parliament, the Swiss government has until the middle of 2024 to "present approval rules on how genetically modified organisms without foreign genetic material can be exempted from the moratorium."[325] Switzerland may have more flexibility for unilateral changes since it is not an EEA member, but Switzerland's participation in the E.U. single market is governed by a series of over 100 bilateral agreements, some of which require Switzerland to follow E.U. legislation.[326]

Other "edge of E.U." possibilities are not as promising. Turkey has a broken regulatory approval process for biotechnology products; the process can take years despite regulations indicating decisions are due in 270 days.[327] Ukraine has an incomplete regime regarding GMO and gene-edited foods that awaits further clarification, but its FTA with the E.U. and other indications suggest it might enact a system quite akin to the E.U.[328]

It will also be important for the United States to negotiate pro-gene-edited crop and food provisions into any new-style non-comprehensive trade agreement with Kenya. As discussed earlier, African countries face subtle but persistent pressure from the E.U. to follow its regulatory model on GM and gene-edited crops and foods.[329] Given Kenya's key role in the African Continental Free Trade Agreement (AfCFTA) that entered into force in January 2021[330] (and now has forty-six countries party to it) but has no

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323 *See* EURO. COMM'N, *Access2Markets: Switzerland*, EURO. UNION, https://trade.ec.europa.eu/access-to-markets/en/content/european-economic-area-eea-agreement (last visited Sept. 25, 2023) [https://perma.cc/PE9P-585X].

324 *See* 2023 NATIONAL TRADE ESTIMATE REPORT, *supra* note 176, at 376.

325 *See id.*

326 *See* EUR. COMM'N, *Access2Markets: Switzerland*, *supra* note 323.

327 *See* 2023 NATIONAL TRADE ESTIMATE REPORT, *supra* note 176, at 402.

328 *See* 2020 NATIONAL TRADE ESTIMATE REPORT, *supra* note 197, at 495–97.

329 Discussions the author has had with visitors to the University of Nebraska representing African governments.

330 *See* Afr. Union, 13th Extraordinary Sess. at ¶ 2, AU Doc. Ext/Assembly/Decl.1(XIII) (Dec. 5, 2020).

specific provisions on gene-edited crops and food,[331] it will be important to use this opportunity to create pro-gene-editing regulation on the African continent. The fact that the E.U. itself is reconsidering and reviewing how to treat gene-edited crops and foods[332] may make it easier for both the United Kingdom and Kenya to agree to pro-gene-editing provisions within an issue-specific deal with the United States that could be integrated in a comprehensive free trade agreement once the United States resumes negotiating such deals in the coming years.

Since Japan already struck a non-comprehensive trade deal with the United States in 2019[333] and is taking more relaxed approach to gene-edited products than GM ones, it is the ideal primary candidate for the United States to strike a pro-gene-editing issue-specific trade deal with and thereby create momentum within the IPEF negotiations. A deal with Japan, the leading economy in the CPTPP and second largest in Asia,[334] will make it easier to translate gains regionally within the IPEF. If the United States could strike pro-gene-editing deals with Vietnam and the Philippines, both of which were mentioned as future free trade agreement partners prior to the United States turning away from traditional FTA negotiations, this would further gains for gene-edited crops and food in Asia as well as continue momentum within IPEF negotiations. If IPEF trade negotiations conclude soon, it may be that bolder provisions could be included in subsequent bilaterals with Japan, Vietnam and the Philippines. The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), an agreement with twelve parties including Japan, Vietnam, and the Philippines, but not the United States since it declined to join after playing a key role in negotiations, contains very modest provisions on agriculture

331 *See* Afr. Union, Agreement Establishing the African Continental Free Trade Agreement, (Mar. 21, 2018), https://au-afcfta.org/wp-content/uploads/2022/06/AfCFTA-Agreement-Legally-scrubbed-signed-16-May-2018.pdf [https://perma.cc/ZY6U-SWR8].

332 *See supra* notes 211-213 and accompanying text.

333 *See U.S.-Japan Trade Agreement Text*, OFF. OF THE U.S. TRADE REPRESENTATIVE, https://ustr.gov/countries-regions/japan-korea-apec/japan/us-japan-trade-agreement-negotiations/us-japan-trade-agreement-text (last visited Sept. 25, 2023) [https://perma.cc/F5VH-W3HY**]**.

334 *See* Government of Canada, *CPTPP Partner: Japan*, (noting Japan has world's third largest economy behind United States and China), available at tps://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptpgp/countries-pays/japan-japon.aspx?lang=eng.

biotechnology. In essence, the CPTPP notes the benefits of transparency and communication on the issue of trade in agricultural biotechnology products, establishing a working group for discussions, and establishing a procedure for LLP occurrences. But at least countries such as Japan, Vietnam and the Philippines have experience in negotiating and including provisions on agriculture biotechnology in trade agreements. The United States should continue to raise gene-editing and GM issues with China and India in the non-comprehensive trade negotiations with those two countries given their size and importance but progress is likely to be much slower. India is involved in the IPEF negotiations, but not the trade pillar (although there is hope India will join the trade pillar later).[335]

With Australia and New Zealand both engaging in regulatory reform efforts and their common food code body FSANZ also doing so, it would be an ideal time to conclude an FTA amendment with Australia or an issue-specific "side agreement" on gene-edited products and conclude an agreement with New Zealand on the issue too. Some additional pressure from trade negotiations may be constructive to these two countries' respective domestic processes because both are large agricultural exporters and need to be sensitive to adopting too restrictive of an approach on gene-edited crops and food domestically given the need for friendly foreign markets.

The timing and legally binding nature of such deals can be adapted to individual dynamics with entryway countries the United States negotiates with. If the United States believes pro-gene-editing reforms already have sufficient momentum within a country, and trade negotiations on the topic could create political blowback, the U.S. can delay entering an agreement with that country until reforms are concluded and have the agreement serve a 'locking-in' function for the reforms.[336] If the United States believes that a

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335 *See* Amiti Sen, India Weighing Option of Joining Trade Pillar of Indo-Pacific Economic Framework, THE HINDU BUSINESS LINE (Aug. 12, 2023, 7:55 PM), https://www.thehindubusinessline.com/economy/india-weighing-option-of-joining-trade-pillar-of-indo-pacific-economic-framework/article67187741.ece [https://perma.cc/YGP2-T8W9] (discussing the possibility of India joining the Indo-Pacific Economic Framework).

336 Trade agreements have been used to lock-in reforms in the agricultural sector in different contexts. *See* MARY E. BURFISHER & ELIZABETH A. JONES, REGIONAL TRADE AGREEMENTS AND U.S. AGRICULTURE 1 (1998) ("Many recent agreements have locked in

country may need time before it can formally adopt pro-gene-editing regulations (e.g., perhaps with Norway and Switzerland facing limits on unilateral reforms), the United States could enter a political commitment (legally non-binding agreement) initially with that country that could subsequently be turned into a legally binding instrument after reforms. The United States can also use phase-in periods for certain obligations depending on unique circumstances with an entryway country.

Once having established single or multiple pro-gene-editing trade partners via regional non-comprehensive, bilateral non-comprehensive or issue-specific agreements in each region, the United States could seek to later expand those results if reengagement in broader regional FTAs, such as the CPTPP and Transatlantic Trade and Investment Partnership (TTIP) between the E.U. and United States, occurs or U.S. trade politics allows for the resumption of bilateral free trade agreement negotiations.[337] The existence of those momentum-creating entryways into each continent with major markets within those continents can facilitate strong gene-edited crop and food provisions within any future broader regional deals. The United States can, of course, in parallel continue progress within the WTO that was begun with the Argentina-led non-binding pro-gene-editing statement in the WTO SPS Committee. However, progress in the WTO will be much slower. Ultimately, a plurilateral agreement with high standards and a significant number of parties would be a desirable goal within the WTO. The digital trade plurilateral negotiations within the WTO could serve as a model in both its successes and failures.[338] The regional and bilateral deals can also act as a catalyst for a successful WTO plurilateral deal down the road.

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domestic reforms and the opening of economies, reinforcing the goals of globalism for freer trade, greater market access, and global efficiency gains.").

337 On the politics of traditional free trade agreement negotiations that would include market access (tariff-cutting) commitments, see Jill O'Donnell, Public Support: A Missing Variable in the Trade Policy Equation, YEUTTER INST. (Mar. 24, 2023), https://yeutter-institute.unl.edu/public-support-missing-variable-trade-policy-equation [https://perma.cc/JQK9-6DDQ].

338 *See, e.g.*, Arindrajit Basu, Can the WTO Build Consensus on Digital Trade?, THE HINRICH FOUND. (Oct. 5, 2021), https://www.hinrichfoundation.com/research/article/digital/can-the-wto-build-consensus-on-digital-trade/ [https://perma.cc/8L3T-QB6K] (summarizing 2020-21 developments on digital trade within the World Trade Organization).

B. Bold Pro-Gene-Editing Provisions for Inclusion in U.S. Trade Agreements

Once entryway countries and types of agreements have been identified for trade negotiations on gene-edited crops and food, the question will arise as to what specific provisions should be negotiated within the agreements. The United States should pursue bold provisions that go beyond USMCA and China Phase I provisions on gene-edited crops and foods. For example, provisions in future U.S. trade agreements should actually require countries to treat gene-edited crops as conventional crops where no foreign DNA remains in the final product. The most important principles for incorporation into U.S. trade agreements are as follows[339]:

Product-Based Rather than Process-Based Regulation: The United States has taken a product rather than process approach to gene-edited crops and food.[340] This is beneficial for gene-edited crops and food because oftentimes the gene-editing process can achieve the same results as traditional plant breeding but in a much shorter time. As the FSANZ Report indicated, process-based approaches run the risk of treating similar products differently.[341]

Transparency: Transparency is a core provision in many technical standards-related trade agreements.[342] Additional provisions sometimes provide for enquiry points so that questions

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339 *See* Huang et al., *supra* note 25, at 11 (recommending: "1. Minimize the risk of escape of GECs from laboratories and fields during the research and development phase. 2. Demonstrate the absence of foreign sequences, if genome engineering proteins were introduced as DNA constructs. 3. Document DNA sequence changes at the target sites. If new sequences were introduced by homologous recombination, identify the phylogenetic relationship between the donor and recipient, as a proxy for the likelihood of new interactions with genetic background. Sequences from distantly related species introduced into GECs by homologous recombination may have to be considered on a case-by-case basis. 4. Ensure that the primarily targeted site did not suffer unintended secondary editing events and consider the consequences of potential off-target events on the basis of available reference genome information and whole-genome resequencing technologies. 5. Include documentation of the above four points for cultivar registration. Beyond these four points, GECs should only be subject to rules and regulations that apply to products of conventional breeding before commercial release").

340 *See* Ishii & Araki, *supra* note 179, at 45–46 ("[T]he USA is considered to regulate GM crops primarily under 7 CFR Part 340 and Part 360, which imply that the risks associated with GM crops should be assessed based on the final product rather than on the processes involved in producing the product[.]").

341 FOOD STANDARDS AUSTRALIA NEW ZEALAND, *supra* note 187, at 5.

342 *See*, *e.g.*, SPS Agreement, *supra* note 54, at 73.

on regulations can be answered in a timely fashion. In the WTO context, there is dissatisfaction with the level of compliance with transparency and notification obligations.[343] It is often easier to enforce transparency obligations in bilateral or smaller grouping agreements and thus important to include such obligations in any pro-gene-editing trade deals.

Timely Decisions & Right to Appeal: The US-China Phase I deal has specific provisions on timelines for review and decision[344] because that has been a key problem in accessing the Chinese market. However, access to other countries' markets is impacted as well as investment in gene-editing products through delay, and thus it is important to have the issue of timely decisions addressed in all agreements. This is especially important given early agreements will hopefully be expanded to additional countries over time that may use delay to undermine the substance of agreements. Providing a guaranteed right to appeal decisions on gene-edited crop or food approval is important to ensure that obligations are being followed and to ensure oversight and accountability.

Low-Level Presence (Non-Overreaction) Provisions: Both the USMCA and China Phase I contain provisions on LLP events and provide a solid baseline for future agreements.[345] However, the United States, particularly in broader regional agreements, could seek to achieve some harmonization on the level below which it is considered an LLP event. Currently, the EU, Turkey, and other countries maintain miniscule limits (sometimes as low as 0.1%) for unapproved biotechnology traits in food shipments, and this increases the risk of significant disruptions in trade,[346]particularly if unaccompanied by an LLP policy.

Mutual Recognition and/or Harmonization on Approval and Labeling: These provisions could be the core of establishing USMCA-plus (USMCA+) provisions on gene-edited crops and

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343 *See generally*, William Alan Reinsch et al., *CSIS Transparency at the WTO: Why Does Transparency Matter, and Are Members Meeting Their Obligations*, CTR. FOR STRATEGIC & INT'L STUD. (Apr. 22, 2020), https://www.csis.org/analysis/transparency-wto-why-does-transparency-matter-and-are-members-meeting-their-obligations [https://perma.cc/BWZ5-8A4G] (discussing the importance of transparency for proper functioning of WTO).

344 China Phase I Deal*, supra* note 162, at 3–20.

345 *See* USMCA, *supra* note 141, at 3–8; China Phase I Deal*, supra* note 162, at 3–21.

346 *See* 2023 NATIONAL TRADE ESTIMATE REPORT, *supra* note 176, at 160.

food within future agreements. The U.S. regulatory system is quite favorable for gene-edited crops and food products, as such products often receive a green-light.[347] The United States could seek to have other countries join in agreeing to that system, and many countries in the Americas may be ready to do so. Another option is a system where there could be mutual recognition by countries of gene-edited products approved in the other. A bit of a hybrid possibility in response to this concern would be to have broad regional agreements provide for mutual recognition of approval, provided a minimum percentage of market size within the region has already approved of the gene-edited crop or food. That minimum percentage can be set at a level such that the United States would need to approve the product in order for that minimum market percentage to be met. Mutual recognition would also alleviate some of the burden on strained regulatory systems and regulators in developing countries.

One other issue the United States ought to consider is whether to pursue more aggressive mutual recognition and/or harmonization provisions on gene-edited crops and food than with respect to GM crops and food. Some believe that such a plan would be a short-term benefit with long-term consequences, as gene-editing techniques begin to include foreign DNA, even of closely connected plants.[348] However, the current United States regulatory regime on both approval and labeling allows a preferred status for gene-editing techniques that do not leave foreign DNA in the crop or food.[349] Furthermore, gene editing is not subject to as much consumer mistrust as GM's that leave foreign DNA present.[350] There are thus both legal and market-based reasons that will potentially allow bolder provisions on gene editing, such as mutual recognition and/or

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347 GENETIC LITERACY PROJECT, Global Gene Regulation Tracker United States: Crops/Food (last visited Sept. 8, 2023) https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/united-states-crops-food/ [https://perma.cc/6NZT-PKZL].

348 YUETTER INSTITUTE OF INTERNATIONAL TRADE AND FINANCE, THE FUTURE OF U.S. AGRICULTURAL BIOTECHNOLOGY AND TRADE: SUMMARY OF A ROUNDTABLE DISCUSSION (October 2023).

349 *See supra* notes 224-243 and accompanying text.

350 *See, e.g.*, Eunae Son & Song Soo Lim, *Consumer Acceptance of Gene-Edited versus Genetically Modified Foods in Korea*, 18 INT'L J. ENV'T RSCH. & PUB. HEALTH 3805 (2021) (discussing Korean consumer acceptance trends for gene-editing and genetically modified foods).

harmonization around the U.S. standard. All plant breeding technologies are a tool to create genetic variability for the benefit of as many people as possible as quickly as possible. However, legal and market-based considerations virtually necessitate different treatment of gene editing that leaves no foreign DNA remaining in the product and GM that does.

Waiving Advanced Informed Consent Under Cartagena Protocol: As analyzed above, it may well be that many gene-edited products are not LMOs under the Cartagena Protocol. In any event, there are possibilities within the Cartagena Protocol to waiving advanced informed consent on intentional introduction (e.g., seeds) with an agreement between countries depending on whether gene-edited seeds meet the definition of LMO under the Protocol. Regional and bilateral agreements struck by the U.S. could address this issue as well and thereby eliminate any haze of uncertainty that results from Cartagena Protocol's definitional ambiguities.

Blocking Approvals in Gene-Edited Products from Non-Market Economies that Engage in Discriminatory or Non-Transparent Approval Processes and/or Intellectual Property Theft in Gene-Editing Technologies: President Xi of China has claimed that gene-editing and seed technology generally are the semiconductor microchips of agriculture.[351] China is not living up to transparency commitments within the China Phase I deal, essentially approving all domestic biotechnology applications and only a few foreign petitions under the apparent strategy of developing global dominance in the field.[352] Because of the size of the Chinese market, many countries' innovators of gene-editing crops and food would benefit in their commercialization efforts if China's approval process was transparent and de facto non-discriminatory.[353] Until these practices by China change, and with the WTO dispute settlement system fractured and unable to issue binding rulings, the United States should seek inclusion in agreements of provisions that would block approvals of gene-edited products from non-market

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351 *See* Xinhua, *Sowing for Future: Xi Leads China's Seed Industry Vitalization*, CHINA DAILY (Feb. 24, 2022, 8:35PM), https://www.chinadaily.com.cn/a/202202/24/WS6216d2d1a310cdd39bc8889a.html [https://perma.cc/2RWT-3QJJ].

352 *See* FOREIGN AGRIC. SERV., U.S. DEP'T OF AGRIC., NO. CH2022-0112, AGRICULTURAL BIOTECHNOLOGY ANNUAL: CHINA (2022).

353 *See id.* at 8.

economies that engage in these practices. While this may be an uphill-battle, it is a worthy point of negotiation.

Successful negotiations leading to the provisions laid out above in a variety of trade agreements will be of large benefit to agriculture technology developers, not just in the United States, but they will assist also in agriculture sustainability in many other countries as well. Regulators in other countries will be given the political cover they need through these agreements to be advancers of innovation within the implementation and administration of the regulations. These developments will also encourage and give leverage to those governments and non-governmental actors in Europe, Asia, and Africa seeking a much more science-based approach to gene-edited products. Without such an approach, these regions will fall behind on technology and investment.[354] Recent events demonstrate that this realization is starting to occur to policymakers; the European Commission recently introduced a proposal to loosen rules for gene-edited crops and food, although the proposal is not expected to receive approval of the European Parliament and European Council in the near term.[355] There are also calls for Africa to take a more favorable approach to agriculture biotechnology, especially with the AfCFTA in force.[356]

Of course, provisions in U.S. regional and bilateral trade agreements liberalizing gene-edited crop and food regulation, both with respect to approvals and labeling, will not in itself be enough to ensure fair treatment of gene-edited products. The GM situation has shown that consumer (mis)perception and politics can

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354 *See, e.g.*, Max Planck Gesellschaft, *Scientists Call for Modernization of EU Gene-Editing Legislation* (July 29, 2019), https://www.mpg.de/13761643/scientists-call-for-modernization-of-the-european-genetic-engineering-law [https://perma.cc/5UW9-EXXS] (discussing letter from 117 European scientific organizations and claiming the EU's current approach to gene-editing "makes investment in research and development in Europe unattractive. As a result, Europe will fall behind in international competition for the development of new varieties with improved characteristics.").

355 *See* Erik Stokstad, *European Commission Proposes Loosening Rules for Gene-Edited Plants*, SCIENCE, (July 7, 2023), https://www.science.org/content/article/european-commission-proposes-loosening-rules-gene-edited-plants [https://perma.cc/WRZ8-GB4Q].

356 Tlou S. Masehela & Eugenia Barros, *The African Continent Should Consider a Harmonized Consultative and Collaborative Effort Towards Coordinated Policy and Regulatory Guidelines Across the Field of Agriculture Biotechnology*, 11 FRONTIERS IN BIOENG'G & BIOTECH. 1, 1 (2023).

occasionally overcome international legal obligations on the ground. Businesses of all sizes and scientific organizations need to coordinate with one another and with governments on a communication effort that can be implemented domestically and internationally. While the "transfer of controversies from GM to genomics" may seem "particularly ironic, since plant scientists consider genomics often as an uncontroversial alternative to GM,"[357] there is a real risk of such an occurrence. One study shows that consumer views of gene editing depend on whether it is correlated more with GMO or more with conventional breeding:

> Indeed, it has been shown that when people are confronted with the name genomics this makes them evaluate related information in a similar way to genetic modification. Importantly, when the term genomics was replaced with the term natural crossing their evaluations were more similar to those for traditional breeding (and, for that matter, more favourable).[358]

Trade agreement provisions and such communication efforts are mutually supportive because the relationship between regulation and perception is a two-way street. The ECJ ruling finding that gene-edited products are subject to GMO regulation "has the potential to trigger a classification effect, by which societal debates around NPBTs [New Plant Breeding Technologies] will quasi-automatically be put in the same basket as debates surrounding GMs."[359] A study of gene-edited food perceptions among Japanese youth similarly found "the importance of increasing knowledge and the positive role of science communication in increasing the adoption and trust of biotechnology products, such as genetically edited food."[360] Studies on Chinese stakeholders, including consumers, also show that greater knowledge is important to acceptance of new food technology.[361]

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357 *See* Reginald Boersmaet al., *The Elephant in the Room: How a Technology's Name Affects Its Interpretation*, 28 PUB. UNDERSTANDING SCI. 218, 219 (2018).

358 *See* P. Marijn Poortvliet et al., *On the Legal Categorisation of New Plant Breeding Technologies: Insights from Communication Science and Ways Forward* 7 (Wageningen U. & Rsch. Working Paper No. 4, 2018).

359 *Id.* at 9.

360 Mohamed Farid et al., *Exploring Factors Affecting the Acceptance of Genetically Edited Food Among Youth in Japan*, 17 INT'L. J. ENV'T RSCH. & PUB. HEALTH 1, 1 (2020).

356 *See* Kai Cui & Sharon P. Shoemaker, *Public Perception of Genetically-Modified (GM) Food: A Nationwide Chinese Consumer Study*, 2 NPJ SCIENCE FOOD 1, 6 (2018).

361 *See* Zhao et al., *supra* note 166, at 1.

VI. Labeling of GM and Gene-Edited Food

Beyond approval of the sale and importation of gene-edited food is the issue of labeling. Over sixty countries have some mandatory labeling of GM food,[362] but there is a wide variety of requirements and significant differences in the amount of GM ingredients that would trigger the labeling requirement. The United States has joined the list of countries that mandate labeling. On January 1, 2022, the labeling of GM food became mandatory in the United States, although under the U.S. regulation, they are referred to not as GM but instead as "bioengineered."[363] Many large companies already started using such labels during a period of implementation and voluntary compliance with the National Bioengineered Food Disclosure Standard (NBFDS).[364] The NBFDS was finalized on December 20, 2018,[365] and the standard was required by Congress' July 2016 National Bioengineered Disclosure Law.[366] The 2016 federal law was passed partially in response to a Vermont law requiring GMO labeling and worries that there might be a variety of approaches adopted by different states within the United States.[367] Under the NBFDS, "bioengineered food" means:

> (i) A food that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in

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362 *See Genetically Engineered Food Labeling Laws*, CTR. FOR FOOD SAFETY, https://www.centerforfoodsafety.org/ge-map/ (last visited Sept. 25, 2023) [https://perma.cc/L4M3-N96X].

363 Melissa Waddell, *What You Need to Know About Bioengineered (BE) Food Labeling*, NON-GMO PROJECT (May 26, 2021), https://www.nongmoproject.org/blog/what-you-need-to-know-about-bioengineered-be-food-labeling/ [https://perma.cc/AW9H-JPRH].

364 *See* Elaine Watson, *Many Stakeholders Not Yet Up to Speed on National Bioengineered Food Disclosure Standard, Experts Say*, FOOD NAVIGATOR USA (updated May 11, 2021), https://www.foodnavigator-usa.com/Article/2021/04/13/Many-stakeholders-not-yet-up-to-speed-on-National-Bioengineered-Food-Disclosure-Standard-say-experts# [https://perma.cc/QJ47-R9ST].

365 National Bioengineered Food Disclosure Standard, 7 C.F.R. § 66 (2018) [hereinafter *NBFDS*].

366 S. 764, 114th Cong. § 293 (2016).

367 *See* Jordan James Fabroni, *A Federal GMO Labeling Law: How it Creates Uniformity and Protects Customers*, 32, BERKELEY TECH. L. J. 563, 570–74, 572–73 (2017) (discussing the intention of creating uniformity through federal preemption of state labeling laws with the enactment of a federal GMO labeling law).

nature; *provided that*

(ii) Such a food does not contain modified genetic material if the genetic material is not detectable[.][368]

Gene-edited food will generally not fall under this definition either because the gene-editing technique does not involve in vitro rDNA technique and/or because the modification could be obtained through conventional breeding or found in nature.[369] Many gene-editing techniques, such as CRISPR and TALEN, do not involve in vitro rDNA techniques[370] or lead to results—albeit quicker—that could be obtained through conventional breeding.[371] Some commenters on the draft regulation argued for a broader definition that would include gene-edited products;[372] however, USDA rejected interpreting the law in that fashion in its regulatory definition, which tracks the definition used in the law.[373] USDA also noted that the regulatory definition focuses primarily on the product created by the technology, not technologies themselves, and neither specifically included or excluded any particular technology from the definition.[374] USDA thereby maintains freedom to assess any product arising from a new breeding technology under the regulatory definition.

While the NBFDS ensures that labeling within the United States will be subject to a harmonized federal approach as the federal law preempts states from mandating gene-edited food labels,[375] internationally there is no such harmonization. In addition to the EU, other countries' laws make clear that gene-edited food must be labeled. For example, Malaysia's labeling law captures products in the following circumstances: (a) if the product contains detectable recombinant deoxyribonucleic acid (DNA); or (b) where the profile, characteristic or properties of the product is or are no longer equivalent to its conventional counterpart, irrespective of the

368 7 C.F.R. §66.1.

369 *See id.*

370 *See* National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,835 (Dec. 21, 2018) (to be codified at 7 C.F.R. pt. 66).

371 *See id.* at 65,816.

372 *See id.* at 65, 35.

373 *See id.*

374 *See id.* at 65,816.

375 7 U.S.C. § 1639i(b).

presence of the recombinant deoxyribonucleic acid (DNA).[376] Thus, even if no "foreign" DNA remains in the product after a gene-editing process, such as with CRISPR, the resulting product will arguably need labeling since its profile is no longer equivalent to its conventional counterpart.

The NBFDS also contains exemptions to what is encompassed by "bioengineered food," including an exemption for a "food in which no ingredient intentionally contains a bioengineered (BE) substance, with an allowance for inadvertent or technically unavoidable BE presence of up to five percent (5%) for each ingredient."[377] The exemption for foods that have a bioengineered presence of "up to 5% for each ingredient" is a much higher allowance of unintentional bioengineered presence than found in many other national laws and regulations around the globe. For example, the E.U. sets the allowable non-intentional or accidental level at 0.9%[378] and the Australia New Zealand Food Standards Code at 1%.[379] However, even some countries with lower thresholds allow 5% in specified circumstances,[380] and other major trading partners including Japan and South Korea have general thresholds closer to or matching the United States' chosen level of 5%.[381] USDA selected the 5% threshold under the following rationale:

> this approach appropriately balances providing disclosure to consumers with the realities of the food supply chain. A threshold amount of 5 percent allows BE and non-BE production systems to coexist, whereas a lower threshold, such as 0.9 percent, may increase the regulatory burden for producers and food processors. Any disruption or increased burden on the food supply chain may unnecessarily increase the cost of producing food, and that cost may ultimately be passed on to consumers. To the degree that

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376 Biosafety Act, 2007(Act No. 678/2007) (Malay.).

377 7 C.F.R. § 66.5(c).

378 Directorate-General for Health and Food Safety, *Traceability and Labelling*, EURO. COMM'N, https://food.ec.europa.eu/plants/genetically-modified-organisms/traceability-and-labelling_en (last visited Sept. 8, 2023) [https://perma.cc/7HKJ-G5LF].

379 *See Genetically Modified (GM) Food Labelling*, FOOD STANDARDS AUSTRALIA NEW ZEALAND, https://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx (last visited Sept. 10, 2023) [https://perma.cc/C3CA-CVD5].

380 *See* National Bioengineered Food Disclosure Standard, 83 Fed. Reg. at 65,824.

381 *See id.* at 65,848.

> some production systems and supply chains have already adopted a threshold lower than 5 percent for purposes of voluntary labeling, continued compliance with a lower threshold for the inadvertent or technically unavoidable presence of a BE substance would meet the requirements of the NBFDS. . . .
>
> AMS reiterates that the threshold is intended to allow for coexistence among BE and non-BE crops, and nothing about the threshold amount is meant to convey anything related to health, safety, or environmental attributes of BE food as compared to non-BE alternatives. This rule is intended only to provide a mandatory uniform national standard to equip consumers with information for their personal use.[382]

While commentators worried that the 5% threshold would harm efforts for mutual recognition agreements with other countries given the prevalence of lower thresholds by many countries, USDA believed that the 5% threshold properly balanced the regulatory burden on industry with the benefits to consumers. USDA also found that U.S. exporters already had systems in place to comply with foreign bioengineered labeling standards such that the impact on trade would not be significant.[383]

The NBFDS lays out graphics for the "bioengineered food" label—it is green in color with some yellow for rows of crops and the sun, although a black and white version is also permitted.[384] It can be characterized as a much more friendly label graphic and color choice than that found in some other countries, even other countries with significant bioengineered production. For example, Brazil faces criticism of its GM label that is a black "T" (for transgene) inside a yellow triangle that looks like it is warning of a hazard.[385] The United States comparatively "friendly" label is no surprise given that the rule states "bioengineered food **...** shall not be treated as safer than, or not as safe as, a non-bioengineered counterpart."[386] As required by the law, the NBFDS is the lone standard, and the FDA no longer has authority to regulate voluntary

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382 *See id.* at 65,824.

383 *See id.* at 65,851.

384 *See* Watson, *supra* note 374 (picture at beginning of article).

385 *See* Mark Lynas, *Viewpoint: Brazil GMO Label Shows Need to Balance Transparency and Science*, GENETIC LITERACY PROJECT (May 1, 2018), https://geneticliteracyproject.org/2018/05/01/viewpoint-brazil-gmo-label-shows-need-to-balance-transparency-and-science/ [https://perma.cc/763S-W29K].

386 *See* National Bioengineered Food Disclosure Standard, *supra* note 380 at 65,825.

labeling of bioengineered food.[387] The FDA still issues guidance for voluntary labeling regarding claims that a food product does not contain genetically engineered content, most recently updating that guidance in March 2019.[388] That guidance discourages use of the terms "genetically modified" or "GM," instead encouraging the terms "genetically engineered, "GE" and "bioengineered."[389] FDA states that those terms "describe the use of modern biotechnology" and defines modern biotechnology as "the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection of plants."[390] The guidance does not specifically address gene-edited foods, and thus negative claims about gene editing are not specifically covered in the guidance.[391] In fact, the definition used for modern biotechnology would exclude all or most gene editing techniques.

Canada and Mexico still do not have a mandatory labeling law for GM food generally.[392] In Canada, health and safety reasons will dictate whether a label is required regardless of the production process for the food and its ingredients.[393]

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387 *See* OFF. OF MGMT. & BUDGET, VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DERIVED FROM GENETICALLY ENGINEERED PLANTS: GUIDANCE FOR INDUSTRY 3 (2019).

388 *See id.*

389 *See id.* at 8.

390 *See id.* at 4.

391 *See generally id.* (focusing on the labeling of genetically engineered foods without discussion of gene-edited foods).

392 *See Novel Foods: Labelling Genetically Modified Foods*, GOV'T OF CAN. (May 18, 2022), https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/labelling.html [https://perma.cc/Q49T-7NJU]; *GE Food Labeling: International Food Labeling Laws*, CENTER FOR FOOD SAFETY, https://www.centerforfoodsafety.org/issues/976/ge-food-labeling/international-labeling-laws (last visited Sept. 8, 2023) [https://perma.cc/S2L9-VQKG].

393 *See* GOV'T OF CAN., *supra* note 400.

A. International Labeling Standards

Codex Alimentarius (or "Codex" for short) does not have a standard requiring labels for GM products generally.[394] Rather, it only has mandatory labels for actual human health risks such as required labels for "contains gluten" and "gluten free."[395] In regard to GM food, Codex merely acknowledges that labeling might be part of a risk management strategy.[396] The Codex definition for modern biotechnology is the following: "(i) in vitro nucleic acid techniques, including rDNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection."[397] Some commenters during the regulatory process leading to the NBFDS stated that "the Codex Alimentarius definition of bioengineering is internationally recognized by the World Trade Organization as the standard for settling trade disputes," and therefore should serve as a guidepost for the USDA.[398] However, the USDA did not adopt the Codex definition, in part feeling constrained by the statutory definition Congress adopted.[399] Similarly, the Cartagena Protocol also does not require labeling of GM food at point of sale, but merely recommends use of labels for living modified organisms (LMOs)

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394 *See Genetically Modified Food: International Development in Labeling of GM Food*, CTR. FOR FOOD SAFETY, THE GOV'T OF THE HONG KONG SPECIAL ADMIN. REGION (Sept. 2, 2021), Codex Alimentarius Commission https://www.cfs.gov.hk/english/programme/programme_gmf/programme_gmf_gi_info4.html [https://perma.cc/5KC2-9ELV].

395 *See generally* INT'L SPECIAL DIETARY FOODS INDUS., GUIDANCE ON GLUTEN-FREE LABELLING MEDICAL & ADULT DIETETIC NUTRITION Based on STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN CODEX STAN 118-1979 (2018) ("[P]rovides the international background regarding the labelling of gluten-free food.").

396 *See Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, CODEX PRINCIPLES AND GUIDELINES ON FOODS DERIVED FROM BIOTECHNOLOGY 1 (2003), paras. 9-15. https://mobil.bfr.bund.de/cm/343/codex_principles_and_guidelines_on_foods_derived_from_biotechnology.pdf [https://perma.cc/JN96-NNS6].

397 *See id*. at para. 8.

398 *See* National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65814, 65835, December 21, 2018.

399 *See id.*

crossing national boundaries.[400]

B. International Trade Agreement Constraints on National Labeling Regimes

The World Trade Organization (WTO) agreements and U.S. FTAs (or non-comprehensive agreements) are potential sources of current constraints on national labeling laws concerning GM or gene-edited foods. The possible WTO agreements that might impact labeling laws are the GATT, the Sanitary and Phytosanitary (SPS) Agreement and the Technical Barriers to Trade (TBT) Agreement. There is some debate over whether all or only some of these agreements would apply in a particular case of labeling laws concerning GM or gene-edited food.[401] The SPS Agreement states that a measure in conformity with it will be presumed to be in conformity with the GATT.[402] The SPS Agreement also states "[n]othing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement."[403] The TBT Agreement states that "the provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures."[404] Thus, it is critical to determine the scope of the SPS Agreement.

The SPS Agreement says that the agreement applies "to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement."[405] It further states that "[f]or the purposes of this

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400 *See Pocket K No. 8: Cartagena Protocol on Biosafety*, INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS (ISAAA) (July 2004), https://www.isaaa.org/resources/publications/pocketk/8/default.asp [https://perma.cc/87QQ-VTAT].

401 *See Understanding the WTO Agreement on Sanitary and Phytosanitary Measures*, WTO (May X, 1998), https://www.wto.org/english/tratop_e/sps_e/spsund_e.htm [https://perma.cc/Q6W3-FT4G].

402 SPS Agreement, *supra* note 54, at art. 2, para. 4.

403 SPS Agreement, *supra* note 54, at art. 1.

404 Agreement on Technical Barriers to Trade, 1868 U.N.T.S. 120, at art. 1.5 [hereinafter TBT Agreement] https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm [https://perma.cc/SJQ5-FQ26].

405 SPS Agreement, *supra* note 54, at art. 1.

Agreement, the definitions provided in Annex A shall apply."[406] Annex A then states in its definitions:

> Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and *labelling requirements directly related to food safety*.[407] [emphasis added.]

This last clause is the only mention of "label" or "labeling" within the SPS Agreement. According to Annex A, a labeling requirement directly related to food safety comes within the confines of the SPS Agreement and would need to be scientifically justified and based on a risk assessment or justified by the limited scope precautionary principle built into Art. 5.7 of the SPS agreement that requires countries to seek out the necessary scientific information within a reasonable period of time. However, many GM labeling requirements (including those that capture gene-edited foods) are likely not directly related to food-safety,[408] nor can they be scientifically justified or fit within the scope of 5.7's limited precautionary principle. Apart from an allergy justification, the labeling laws appear to be based more on a "consumer right to know" justification or an ethical or environmental justification. On the consumer right to know rationale, Jonathan Latham—executive director of the Bioscience Resource Project, a New York-based non-profit organization—expresses the view that "if you want people to make informed decisions and you want them to make [them] in a democratic fashion, then the more information you give them, the better. . . . And so to deny people information about the content of their food is to violate a very basic democratic right."[409] As regards

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406 *See id.*

407 SPS Agreement, *supra* note 54, at Annex A.

408 *See* Charnovitz, *supra* note 89, at 296.

409 Ira Basen, *Gene Editing Could Revolutionize the Food Industry, but It'll Have to Fight the PR War GMO Foods Lost*, CBC (Jan. 15, 2020), https://www.cbc.ca/radio/thesundayedition/the-sunday-edition-for-january-12-2020-1.5416826/gene-editing-could-revolutionize-the-food-industry-but-it-ll-have-to-fight-the-pr-war-gmo-foods-lost-1.5416827 [https://perma.cc/BJ23-67UD].

the environmental justification, an example of a concern is the worry over potential increased weed risk, either by a herbicide-resistant, gene-edited crop's gene transferring to wild relatives or hybrids or by increased herbicide use leading to unrelated herbicide resistant weeds.[410] Thus, in the vast majority of cases, it appears labeling requirements for GMs (including those that purport to capture gene-edited foods within their scope) fall outside the SPS Agreement's scope. Of course, there is an interesting case where both a food safety rationale and other rationale are at the root of a labeling requirement and whether in that scenario a measure could be subject to examination under both the SPS agreement and the TBT agreement. One argument against a labeling measure being subject to review under both agreements in such a scenario is the "directly related" to food safety requirement in Annex A to the SPS Agreement and the mutual exclusive provisos contained in both agreements.[411]

The TBT Agreement prevails over the GATT if there is an inconsistency between the two agreements. Interpretive Note to Annex 1A of the WTO Agreement provides that "[i]n the event of conflict between a provision of the General Agreement on Tariffs and Trade 1994 and a provision of another agreement in Annex 1A to the [WTO Agreement], the provision of the other agreement shall prevail to the extent of the conflict."[412]

The TBT agreement applies to both technical regulations (defined as mandatory) and technical standards (defined as voluntary). The definitions of both appear to restrict coverage to "product characteristics and related process and production methods" but then state they include "labelling requirements as they apply to a product, process or production method."[413] Therefore, there is some debate over whether a regulation purely addressing a process or production method unrelated to a product characteristic falls within the definition. Labeling requirements for GM foods

410 *See* Jennifer Kuzma, *Regulating Gene-Edited Crops*, ISSUES IN SCI. AND TECH. (2018), https://issues.org/regulating-gene-edited-crops/ (last visited Sept. 16, 2023) [https://perma.cc/HKT4-6E5K].

411 SPS Agreement, *supra* note 54, Annex A and art. 1(4); TBT Agreement, supra note 404, at art. 1.5.

412 Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154 Annex 1A [hereinafter WTO Agreement].

413 TBT Agreement, *supra* note 404, at annex 1.

would appear to be a "technical regulation" pertaining to a product characteristic (e.g., foreign DNA,) but gene-edited food product labels may not be product characteristic ones (e.g., a silenced gene). Instead, gene-edited product labels may be considered tied to a production process method (PPM), and the WTO Appellate Body left open as to when those are covered by the TBT agreement.[414] The TBT explicitly states that all products, "including industrial and agricultural products, shall be subject to the provisions of this Agreement."[415]

The two central obligations of the TBT Agreement that have been analyzed in WTO Appellate Body jurisprudence are Articles 2.1 and 2.2. These were analyzed in a flurry of WTO cases in the 2012-2014 time period in which four cases with TBT claims reached the Appellate Body, including two dealing with labels: U.S.-Tuna (involving the mandatory use of voluntary "dolphin-safe" labels), U.S. - COOL (involving mandatory labeling of country of origin for meat products), U.S. – Clove Cigarettes (involving ban of clove cigarettes); and EU--Seal Products (involving ban on seal products.).[416] TBT Articles 2.1 and 2.2 provide the following obligations:

> 2.1. Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be

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414 Gabriel Marceau, *A Comment on the Appellate Body Report in EC—Seal Products in the Context of the Trade and Environment Debate*, 23 REV. OF EURO. CMTY. & INT'L ENV'T L. 318, 327-328 (2014).

415 TBT Agreement*, supra* note 404*,* at art. 1.

416 *See generally* Appellate Body Report, *United States–Measures Affecting the Production and Sale of Clove Cigarettes* WT/DS406/AB/R (adopted May 22, 2014) [hereinafter *US-Clove*]; Appellate Body Report, *United States –Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, WT/DS381/AB/R (adopted June 13, 2012) [hereinafter *US – Tuna II*]; Appellate Body Report, *United States – Country of Origin Labelling (COOL) Requirements*, WT/DS384;AB/R & WT/DS386/AB/R (adopted July 23, 2012) [hereinafter *US- COOL*]; WTO Appellate Body Report, *European Communities – Measures Prohibiting the Importation and Marketing of Seal Products*, WT/DS400/AB/R & WT/DS401/AB/R (adopted June 18, 2014) [hereinafter *EU-Seals*]. *See* Panel Report, *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS435/R; WT/DS441/R; WT/DS458/R; WT/DS467/R (adopted June 29, 2018) for a fifth case involving the TBT agreement arose in 2018 dealing with Australia's plain packaging requirements for tobacco products led to a panel report but was not appealed and thus did not result in Appellate Body consideration.

> accorded *treatment no less favourable* than that accorded to *like products* of national origin and to *like products* originating in any other country.
>
> 2.2. Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, *technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective*, taking account of the risks non-fulfilment would create. Such *legitimate objectives are, inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products.

There has been much debate on how TBT analysis under these two articles compare with the analysis of labeling laws that would occur under the GATT framework, specifically an analysis under Art. III:4 (the national treatment obligation) and, if a violation is shown of that article, a possible defense under Art. XX (the general exceptions clause).[417] On its face, analysis under the TBT Agreement can be viewed as more lenient than the GATT because its list of legitimate objectives is wider in scope than under GATT Art. XX, but perhaps more stringent because any technical regulation must survive both 2.1 and 2.2, and 2.1 is worded very similarly to Art. III:4 but without benefit of any Art. XX defense. A further analysis of the WTO Appellate Body jurisprudence is necessary to see the contours of 2.1 and 2.2, and a review of the jurisprudence probably shows that regulating nations face slightly less maneuverability under the TBT than GATT, despite initial indications to the contrary.

For article 2.1, the WTO Appellate Body has ruled that in order

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417 *See generally*, Robert Howse, *The WTO Appellate Body Ruling In Seals: National Treatment Article III;4*, INT'L ECON. LAW AND POL'Y BLOG (May 23, 2014), https://worldtradelaw.typepad.com/ielpblog/2014/05/the-wto-appellate-body-ruling-in-seals-national-treatment-article-iii4.html [hs://perma.cc/UNV4-PCS2]. *See generally* Marceau, *supra* note 414; Robert Howse, Joanna Langille, & Katie Sykes., *Sealing the Deal: The WTO Appellate Body Report in EC—Seal Products*, 18 AM. SOC'Y OF INT'L INSIGHTS no. 12 (June 4, 2014) https://www.asil.org/insights/volume/18/issue/12/sealing-deal-wto's-appellate-body-report-ec-–-seal-products [https://perma.cc/7QCW-JVMZ]; Petros Mavroidis, *Sealed with a Doubt: EU, Seals, and the WTO*, 6 EURO. J. RISK REGUL. 388 (2015).

for a measure to be found a violation the plaintiff must show that the measure has caused a detrimental impact on competitive opportunities for the imported like products as compared to the domestic like product and, further, that the detrimental impact does not arise exclusively from a "legitimate regulatory distinction, i.e. that the measure is not designed or applied in an even-handed manner."[418] Thus, "likeness" of products must be considered and whether there is "less favorable treatment" to the imports—those are the two central elements of a TBT 2.1 claim.[419]

The Appellate Body has affirmed—similar to analysis under GATT Art. III—that "likeness is about the 'nature and extent of a competitive relationship between and among products.'"[420]It has thus incorporated the traditional four-criteria analysis for like products (used in GATT Art. III and other GATT articles) into TBT 2.1, whereby a product's end-uses, consumer tastes, natural properties and qualities, and tariff classification are to be looked at in the analysis.[421] For GM or gene-edited food versus their conventional counterparts, end-uses and tariff classifications (at least tariff classifications employed by most countries) are the same. In terms of natural properties and qualities, there is no difference other than the presence of foreign DNA in the case of GM food and a slightly different gene sequence or a knocked-out gene (with no foreign DNA) in most gene-edited cases. Unless there is a risk to human health or some other significant risk, it is unlikely these differences between GM and conventional crops and food—or certainly between gene-edited and conventional crops and food—could be found significant enough to point towards unlike products. In the *EC-Asbestos* case, the Appellate Body recognized that a health or toxicity difference, due to the presence of asbestos among otherwise similar cement products, could influence a finding of unlike products under the consumer taste and natural properties

418 *See* US – Clove, *supra* note 416, at para. 182; US – Tuna II, *supra* note 408, at para. 215; US – COOL, *supra* note 408, at para. 271.

419 See US- COOL, *supra* note 416, para. 267 (also stating the initial element that the measure be a technical regulation).

420 See US -Clove, *supra* note 416, para. 111.

421 *See* WORLD TRADE ORG., WTO ANALYTICAL INDEX: *GATT 1994 – ART III (DS REPORTS)* 17-18 (2023), https://www.wto.org/english/res_e/publications_e/ai17_e/gatt1994_art3_jur.pdf [https://perma.cc/YNN7-GULS].

criteria,[422] but that factual scenario is the polar opposite of gene-edited products that often could be created through conventional breeding over a much longer timeframe. This would leave consumer taste as a lone factor that might cut against a finding of like products between a gene-edited crop and food and its conventional counterpart in certain countries where consumer preferences have hardened, perhaps based on long-standing regulatory distinctions such as in the EU. However, gene editing is so new that consumer preferences are unlikely to have hardened against gene-edited products in many countries to nearly the same degree as GM food. Additionally, the Appellate Body in *US-Clove Cigarettes* made clear that WTO panels "should determine the nature and the extent of the competitive relationship for the purpose of determining likeness in isolation from the measure at issue, to the extent that the latter informs the physical characteristics of the products and/or consumers' preferences."[423]

The second of the two major elements of a TBT 2.1 claim, focusing on "less favorable treatment," was elaborated on by the Appellate Body in *US-COOL*: "where a regulatory distinction is not designed and applied in an even-handed manner . . . that distinction cannot be considered 'legitimate.'"[424] The Appellate Body has further stated: "In making this determination, a panel must carefully scrutinize the particular circumstances of the case, that is, the design, architecture, revealing structure, operation, and application of the technical regulation at issue, and, in particular, whether that technical regulation is even-handed, in order to determine whether it discriminates against the group of imported products."[425] In *U.S.-Clove Cigarettes*, the Appellate Body held that "the context and object and purpose of the TBT Agreement weigh in favour of reading the 'treatment no less favourable' requirement of Article 2.1 as prohibiting both *de jure* and *de facto* discrimination against imported products, while at the same time permitting detrimental impact on competitive opportunities for imports that stems exclusively from legitimate regulatory distinctions."[426] For

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422 WTO Appellate Body, *EC – Measure Affecting Asbestos and Asbestos Containing Products*, WT/DS135/AB/R March 12, 2001, paras. 133-148 [hereinafter EC – Asbestos]

423 *See* US-Clove, *supra* note 416, at para. 111.

424 *See* US-COOL, *supra* note 416, at para. 293.

425 US-Clove, *supra* note 416, at para. 182.

426 *Id.* at para. 175.

mandatory GM labeling laws (including those that purport to cover gene-edited goods), it is likely that there is a detrimental impact on competitive opportunities for the group of imported products if the imports from the complaining member are wholly or largely gene-edited and the domestic product is largely non-gene-edited. The Appellate Body has made clear that the imports from a complaining country as a group must be compared to the domestic like product as a group.[427] Particularly where no foreign DNA remains in the final product, it will be hard to argue that the detrimental impact "stems exclusively from legitimate regulatory distinctions."[428] The fact that in a labeling regime there is an element of private choice involved in choosing non-gene-edited (or non-GM) products will not relieve a country from liability under TBT Art. 2.1. The Appellate Body held in the *US-COOL* case that "while detrimental effects caused *solely* by the decisions of private actors cannot support a finding of inconsistency with Article 2.1, the fact that private actors are free to make various decisions in order to comply with a measure does not preclude a finding of inconsistency. Rather, where private actors are induced or encouraged to make certain decisions *because of the incentives created by a measure*, those decisions are not 'independent' of that measure."[429]

In analyzing whether a violation of 2.2. has occurred, the Appellate Body TBT jurisprudence indicates that three steps must take place:

> 1. [I]dentify the "objectives" of the measure and determine whether the objective is "legitimate";
>
> 2. [E]valuate the degree to which the measure "fulfils" the objective;
>
> 3. [D]etermine whether or not the measure is "necessary" to fulfil the legitimate objective, taking account of its trade-restrictiveness, the risks of non-fulfilment, and possible alternatives.[430]

In the determination of legitimate objectives, those listed in TBT Art. 2.2 can be looked at as well as those in preambular recitals 6

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427 *See id*. at paras. 190–94.

428 *See* US-COOL, *supra* note 416, at para. 272.

429 *See id*. at para. 1.294.

430 Gabrielle Marceau, *The New TBT Jurisprudence in* US – Clove Cigarettes*, WTO* US – Tuna II*, and* US – Cool, 8 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 1, 14 (2013).

and 7 of the TBT agreement.[431] Additionally, objectives listed in other WTO agreements may be pointed to.[432] That is an extraordinarily long list of legitimate objectives. TBT Art. 2.2 lists in a non-exhaustive fashion (as indicated by use of the term *inter alia*) the following: "national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment."[433] TBT preambular recitals 6 and 7 list measures "to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices" and protection of "essential security interests."[434] The WTO Agreement lists, for example, "sustainable development."[435] Thus, all these and more might constitute legitimate objectives.

Even with this wide scope, one might ask whether the objectives of mandatory labeling of GM or gene-edited foods is legitimate when not done for health and safety. If, for example, there is an environmental concern over herbicide resistance being transmitted to certain weeds, this would fall under a listed legitimate ground. But is a consumer's right-to-know, even if based on consumer preference that had been hardened or created through regulation itself, or certain ethical views, legitimate grounds? GATT Art. XX(a) allows measures necessary to protect public morals.[436] The Appellate Body has interpreted public morals to mean a community's sense of right and wrong, and seems to give members some leeway in defining the concept.[437] Of course, GATT Art. XX is not part of the TBT agreement, but it may be considered when looking to objectives of another covered WTO agreement.[438] In some markets—most notably the EU—the consumer right-to-know is so entrenched that the United States may need to relent in order

431 *See* US-COOL, *supra* note 416, at para. 370.

432 *Id*.

433 TBT Agreement, *supra* note 404, at art. 2.2.

434 *Id.* at pmbl.

435 *See* WTO, *supra* note 405, at pmbl.

436 General Agreement on Tariffs & Trade 1994, art. XX, Apr. 15, 1994, 1867 U.N.T.S. 190.

437 *See* EU-Seals, *supra* note 408, at para. 5.199.

438 *See supra* note 432-433 and accompanying text.

to achieve better access and quicker approvals.[439] One can also question, however, whether the consumer's right-to-know is a proper justification in many gene-edited cases. For example, what if a gene-edit allows lettuce to grow in dry conditions or allows strawberries to be picked by machine? Would a consumer's right to know support a mandatory label for either of those two things? If not, one might question why a consumer's right-to-know would support a mandatory label signifying that the product was gene-edited.

As is often the case even under GATT XX(a) and (b) jurisprudence, findings of the Appellate Body and panels often hinge on whether the measure is considered "necessary."[440] The term "necessary" plays a key role in TBT Article 2.2. jurisprudence as well. The Appellate Body has ruled under TBT 2.2. that panels are to weigh and balance the following: (1) the measure's degree of contribution to the legitimate objective(s), (2) the trade-restrictiveness of the measure, and (3) the risk that non-fulfillment of the legitimate objective would create.[441] Further, the challenged measure will be compared with reasonably available alternatives.[442] These factors under TBT Art. 2.2. are very similar—indeed near identical —to those laid out by the Appellate Body in GATT Art. XX jurisprudence dealing with exceptions containing the lead word "necessary." There might be some slight differences in approach under the factors; for example, the Appellate Body has ruled that a measure must make a "material contribution" to the objective under Art. XX, but indicates that there may be no specific minimum degree of contribution under TBT Art. 2.2.[443] If this distinction is a real one intended by the Appellate Body, this might indicate TBT Art. 2.2 is slightly less rigid than GATT Art. XX jurisprudence, both

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439 *See* Dirk Heumueller & Tim Josling, *Trade Restrictions on Genetically Engineered Foods: The Application of the TBT Agreement*, *in* THE REGULATION OF AGRICULTURAL BIOTECHNOLOGY 79 (R.E. Evenson & V. Santaniello eds., 2004).

440 *See generally* Robert E. Hudec, *GATT/WTO Constraints on National Regulation: Requiem for an "Aim and Effects" Test*, 32 INT'L L. 619, 637 (1998); Donald H. Regan, *The Meaning of 'Necessary' in GATT Article XX and GATS Article XIV: The Myth of Cost-Benefit Balancing*, 6 WORLD TRADE REV. 347, 347 (2007).

441 *See US – Tuna II*, *supra* note 416, para. 318; See *US-COOL*, *supra* note 416, para. 374.

442 *See US – Tuna II*, *supra* note 416, para. 322; See *US-COOL*, supra note 416, para. 378.

443 *See* Marceau, *supra* note 414, at 325.

in terms of the number of legitimate objectives and in terms of the degree of contribution the measure must make to an objective.

The results of three TBT Agreement decisions released by the Appellate Body in close succession in 2012, including two dealing with labeling issues, indicate that violations of TBT Art. 2.2 will be harder to establish than violations of TBT Art. 2.1.[444] In those three cases, violations of TBT Art. 2.1 were found by the Appellate Body, but the Appellate Body declined to find violations of TBT Art. 2.2 even though the original panels had found TBT Art. 2.2 violations. In some of the cases, the Appellate Body ruled it lacked the necessary information to complete a TBT Art. 2.2 analysis—and some notions of judicial economy crept in conceivably as well—but the net result is that TBT Art. 2.1 was the basis for finding a violation of the TBT agreement by the labeling measures at issue. This suggests that while TBT Art. 2.2 is indeed more flexible than GATT Art. III/XX jurisprudence, TBT Art. 2.1 standing as a separate obligation with no exceptions may create a sterner standard than GATT jurisprudence. This conclusion would change if the Appellate Body (when and if revived) or WTO members (when self-applying WTO norms in the near term) use consumer taste arguments to find GM and non-GM or gene-edited and non-gene-edited products not like products, or find labels based on those distinctions to be legitimate regulatory distinctions.

The TBT agreement, like the SPS agreement, also contains presumptions in favor of technical regulations based on international standards and requires international standards to be utilized unless it would not fulfill the legitimate objectives of the regulation.[445] Specifically, TBT Art. 2.4 and 2.5 provide as follows:

> 2.4. Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.
>
> 2.5 [. . .] Whenever a technical regulation is prepared, adopted

444 In the fourth case, *EC – Seal Products*, the TBT claims were found moot by the Appellate Body. *See Appellate Body – Seals*, *supra* note 416, para. 5.70.

445 *See* TBT Agreement, *supra* note 404, at art. 2.4.

> or applied for one of the legitimate objectives explicitly mentioned in paragraph 2, and is in accordance with relevant international standards, it shall be rebuttably presumed not to create an unnecessary obstacle to international trade.

However, as regards GM labeling and gene-editing labeling, no international standard has been adopted and thus these provisions of the TBT agreement do not currently operate in that context. One should not expect an international standard anytime soon, given the differing views on labeling and approving GM and gene-edited foods.

In sum, it may well be that a WTO case against mandatory labeling of gene-edited foods could prevail in theory under TBT Art. 2.1– but several problems exist trying to counter labeling regimes via WTO litigation. First, the WTO Appellate Body has collapsed as of December 2019 by having its membership fall below the minimum number of Appellate Body members needed to hear an appeal.[446] The U.S. government blocked for several years the reappointment or appointment of new Appellate Body members leading to the collapse, due to the United States' concerns of overreach by the Appellate Body in its jurisprudence, the Appellate Body's failure to live up to procedural timelines in cases, and Appellate Body members hearing cases beyond their terms of office.[447] Thus, any panel report ruling on a GM or gene-edited labeling measure cannot be automatically adopted because losing defendant countries can appeal "into the void" created by the lack of an Appellate Body.[448] As a result, the panel ruling will not be a binding ruling and the WTO Dispute Settlement Body will not automatically authorize retaliation for failure to modify or eliminate a labeling requirement found inconsistent with a WTO Agreement. Second, litigation on the issue risks a backlash and further hardening of positions, and thus the WTO litigation route may not be the best course of action, even if the Appellate Body is revived or the dispute settlement system's ability to issue binding rulings is restored. It appears that the United States made the same conclusion

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446 *See* Schaefer, *supra* note 8.

447 Dennis Shea, *Matters Related to the Functioning of the Appellate Body*, U.S. MISSION GENEVA (Dec. 9, 2019), https://geneva.usmission.gov/2019/12/09/ambassador-shea-statement-at-the-wto-general-council-meeting/ [https://perma.cc/Z7MK-NUQ5].

448 *See* Lester, *supra* note 6.

when it came to challenging the E.U. ban on chlorinated chicken — requesting consultations, but not proceeding with the case through a request for establishment of a panel.[449]The inability to successfully use WTO dispute settlement to challenge gene-editing labels is further support for establishing provisions within U.S. trade agreements on the labeling issue.

C. USMCA Labeling Provisions

USMCA incorporates much of the WTO TBT Agreement, including Arts. 2.1 and 2.2, but adds a specific provision on labeling.[450] It is important to recall that currently neither Canada nor Mexico requires labeling of GM food, let alone gene-edited food. Canada's parliament rejected a bill that would have required mandatory labeling of GM food in 2017[451] but, of course, circumstances could always change. If Canada, or Mexico, decides to change course on mandatory labeling, the United States could seek to have those countries harmonize around the U.S. labeling standard or at least the key aspects of it, specifically exemption (at least in application) of gene-edited foods from labeling requirements, avoidance of the GM terminology (in favor of alternatives like "bioengineered"), and creation of biotechnology-friendly labels that do not indicate hazard or safety concerns.

The USMCA prevents duplicative litigation in both the WTO and under the USMCA's dispute settlement mechanism in a variety of settings. USMCA Article 11.3.2 provides the following:

> No Party shall have recourse to dispute settlement under Chapter 31 (Dispute Settlement) for a matter arising under this [Technical Barriers to Trade] Chapter if the dispute concerns: (a) exclusively claims made under the provisions of the [WTO] TBT Agreement incorporated under paragraph 1; or (b) a measure that a Party alleges to be inconsistent with this Chapter that: (i) was referred

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449 *European Communities — Certain Measures Affecting Poultry Meat and Poultry Meat Products from the United States,* WTO Doc. WT/DS389/4 (Oct. 12, 2009), https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds389_e.htm [https://perma.cc/39RL-KWRW] (finding that a panel was established but no panel ruling ever issued).

450 *See* USMCA, *supra* note 139, art. 3.14.

451 *See Canada's House of Commons Rejects Mandatory Labeling of Genetically Modified Foods*, McMillan LLP, (May 2017), https://mcmillan.ca/insights/canadas-house-of-commons-rejects-mandatory-labeling-of-genetically-modified-foods/ [https://perma.cc/8UFE-RWHU].

> or is subsequently referred to a WTO dispute settlement panel, (ii) was taken to comply in response to the recommendations or rulings from the WTO Dispute Settlement Body, or (iii) bears a close nexus, such as in terms of nature, effects, and timing, with respect to a measure described in subparagraph (ii).[452]

Article 11.3.2 operates essentially as a specific exception to the general rule, established in the dispute settlement chapter of the USMCA Art. 31.1.3, that gives the plaintiff a choice of forum between the USMCA and the WTO (and locks them into that choice once they have requested establishment of a dispute settlement panel under one of the agreements). Sub-paragraph (a) prohibits the United States from bringing a claim against a future Canadian or Mexican labeling measure under USMCA dispute settlement mechanism if the exclusive claim is a violation of the WTO TBT agreement.[453] Sub-paragraph (b) prevents a USMCA case if the case is referred to a WTO panel, presumably even if another party refers it to the WTO. Thus, pursuing dispute settlement for a WTO TBT violation appears not to be any more feasible under the USMCA than it is under the WTO. However, this is where one must pay attention to article 11.5.8, which provides:

> 8. In order to avoid disrupting North American trade, and consistent with the obligations contained in Article 11.3 (Incorporation of the TBT Agreement), each Party shall ensure that its technical regulations concerning labels: (a) accord treatment no less favorable than that accorded to like goods of national origin; and (b) do not create unnecessary obstacles to trade between the Parties.[454]

In a challenge to a labeling measure, one could argue that the claim is not exclusively based on a TBT provision but also USMCA 11.5.8 even though that article basically repeats the major tests of TBT article 2.1 and 2.2 of the TBT. Therefore, a party such as the United States could argue that a claim under the USMCA Art. 31 general dispute settlement provision should not be precluded by application of 11.3.2. How a USMCA panel would rule on that issue remains to be seen, but the inclusion of Article 11.5.8 as a separate article combined with the rule of effectiveness in treaty interpretation—providing that each provision must be so interpreted

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452 USMCA, *supra* note 139, art. 11.3.2.

453 USMCA, *supra* note 139, 11.3.2(a).

454 USMCA, *supra* note 139, at art. 11.5.8.

so as to have meaning or effect rather than being denied meaning[455]—suggests that a future USMCA panel may proceed to hear a labeling measure-based claim based on Art. 11.5.8.

USMCA allows for trade retaliation in response to a measure that has been found inconsistent by a dispute settlement panel if the party found in violation does not remove or change their measure to bring it into conformity, and if the parties cannot agree on some other settlement to the dispute.[456] However, the larger consideration of creating additional backlash or hardening consumer views against GM or gene-edited foods demands caution before bringing a dispute under the USMCA. It also points towards advance negotiations on the issue between the United States and its North American trading partners as a likely more fruitful path. The same applies on the international level. As the United States seeks out countries as entryways via trade agreements for favorable treatment of gene-edited foods, it needs to address the issue of labeling. Avoiding mandatory labeling for gene-edited foods and seeking friendly labels for GM foods, including new terminology other than GM in such labels—all features of the U.S. mandatory labeling regime under the NBFDS—would be key labeling components in any such agreements creating regulatory entryways for gene-edited crops and food in each region of the world.

The United States should pursue mutual recognition agreements and even possible harmonization negotiations on labeling issues with trading partners in its trade agreements. USDA indicated it would pursue mutual recognition agreements with other countries during its NBFDS rulemaking and also acknowledged that it had no such agreements in place yet.[457] Harmonization negotiations that might harmonize labeling standards as close as possible to the current U.S. standard, including a definition that does not encompass most or all gene-edited foods, could also be pursued.

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455 *See, e.g.,* Appellate Body Report, *Argentina – Safeguard Measures On Imports Of Footwear*, WTO Doc. WT/DS121/AB/R, ¶ 81 (adopted Dec. 14, 1999) ("[A] treaty interpreter must read all applicable provisions of a treaty in a way that gives meaning to all of them, harmoniously."); *see also* Appellate Body Report, *United States - Standards for Reformulated and Conventional Gasoline*, WTO Doc. WT/DS2/AB/R, ¶ 21 (Apr. 29, 1996) ("One of the corollaries of the "general rule of interpretation" in the Vienna Convention is that interpretation must give meaning and effect to all the terms of the treaty."); *see also* Serghides, *supra* note 128.

456 USMCA, *supra* note 139, at art. 31.19.

457 *See* NBFDS, *supra* note 365.

The choice of the 5% threshold gives the United States some ability to harmonize around a lower number in future negotiations with a similarly sized trading partner—the European Union in particular—for GM food. The United States may need to consider relenting on the issue of gene-edited food labeling in any negotiations with the E.U. given the market size and leverage of the EU, but should only do so after careful consideration of the economic and trade impacts of labeling, and attempting to use countries such as the UK, and possibly (if permitted under their treaty obligations with the EU) Norway and Switzerland, on the edge of Europe as leverage. Any compromise should ensure that any such label is friendly and not warning of a hazard and should take place only in return for significant liberalization regarding approvals for gene-edited crops and food.

VII. Conclusion

Gene-edited crops and food have the capability to enhance human nutrition, food security and agricultural sustainability. In contrast to GM crops and food, most gene-editing techniques do not leave any foreign or exogenous DNA in the plant (nor in any food products made from the plant). Yet, there is a real risk that gene-edited crops and food will succumb to the negative regulatory treatment and consumer (mis)perceptions that have befallen GM crops and food. Indeed, the EU—the second largest market behind the United States—through court decision has lumped GM and gene-edited crops and food together for the same onerous regulatory treatment. The United States, in contrast, has completed regulatory reform efforts in the past five years that ensure that gene-edited crops will not be subject to restrictive pre-approvals, nor to mandatory labeling. Countries comprising the other roughly 3/5ths of world GDP have taken a variety of approaches. The countries within the Americas, led by Argentina, have largely followed the lead of the United States. Approaches in Africa and Asia vary widely and are still in development.

The best strategy for the United States to ensure a favorable gene-edited crop and food regulatory environment, both in terms of approval and labeling, is to establish pro-gene-editing trade deals via new-styled, noncomprehensive trade agreements or issue-specific trade deals on a regional or bilateral basis in major markets in each continent of the globe. There are good candidates in each

world region based on a variety of factors, including large market size, currently favorable or "under review" gene-editing policy, and the presence of current ongoing negotiations or prospective negotiations on a regional or bilateral new-style noncomprehensive agreement with the United States. WTO litigation will not be an effective strategy to achieve favorable regulatory treatment of gene-edited crops and food due to the collapse of the WTO Appellate Body. Moreover, even if the WTO dispute settlement system is fixed in the near future, there is always a significant risk of backlash or hardening of positions through use of WTO litigation on such issues. However, the United States can use legal arguments indicating the inconsistency of anti-gene-editing approval and labeling measures with WTO commitments in its diplomacy and during negotiations with other countries. Once the United States has established pro-gene-editing entryways in each continent, the United States can seek to expand those pro-gene-editing provisions to broader regional comprehensive deals—when the United States elects to re-engage in those efforts—and/or a WTO plurilateral agreement with broad subscription– when the WTO negotiating pillar revives and strengthens. Importantly, the United States should seek bolder provisions in these new agreements than was achieved in the USMCA and the China Phase I trade deal. Specifically, such agreements should pursue provisions on approval and labeling that harmonize roughly around the U.S. approach and/or incorporate a measure of mutual recognition of gene-edited products.