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The Right to Regulate (Cooperatively)

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ABSTRACT

The growing number of new technologies in food production—such as nanotechnology, genetic modification, animal cloning, and irradiation—are garnering different regulatory responses around the world. Based on their threshold for tolerating risk, countries are asserting their national right to regulate at home using labeling, quarantine, and outright bans on foods. But domestic regulation has its limits in a free trade environment. Countries that are not mindful of treaty obligations could face legal liability, as seen in the recent litigation between Uruguay and Philip Morris International. In short, traditional models of international regulatory cooperation (IRC) are failing to provide countries with sufficient regulatory latitude within a free trade framework.

New Mega-Regional agreements provide a renewed momentum to advance cooperation. In 2012, President Obama issued an executive order to prompt federal agencies to engage in IRC and championed two important IRC initiatives, the Trans-Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partner-

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ship. Obscured by the criticism of the TPP (including by both major parties in the 2016 U.S. Presidential election) is its development of a novel framework that promises to integrate domestic regulatory oversight and free trade goals. As this Article explains, the TPP is (1) an exemplar of a Mega-Regional trade framework, (2) a new promising mechanism for IRC, and (3) a way to achieve higher food safety outcomes. In so doing, it underscores how the TPP enhances regulatory cooperation with a menu of new treaty offerings that nudge countries to regulate in ways unrecognized in the IRC literature. Given the rapid pace of new food technologies, the inability to resolve international conflicts with traditional means, and impending trade disputes, the model of IRC developed in this article provides an effective solution to a growing challenge in the international trade regime.

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1. INTRODUCTION: A NEW REGULATORY WORLD

We are living in a new regulatory reality marked by two growing trends. Across the globe, trade negotiators are busy drafting new trade agreements to expand markets. Meanwhile, at home, food regulators are drafting rules to keep pace with the global development of new food technologies—such as genetic modification, animal cloning, irradiation, and nanotechnology[1]—in an effort to maintain a high level of health and safety protection. Striking the balance between maintaining national policy autonomy while opening markets is an increasing challenge.

Countries have an inherent right to regulate in the public interest, a basic act of sovereignty under international law,[2] and they do so with varying levels of protection depending on the risk-tolerance levels of the nations' respective citizenries. While this fundamental right to regulate is recognized in most free trade agreements,[3] it has limits. A new wave of international lawsuits

[1] *See e.g.*, Letter from Rosa L. DeLauro et al., U.S. House of Representatives, to Michael Froman, Ambassador, U.S. Trade Representative (Oct. 21, 2015) http://delauro.house.gov/images/pdf/03.19.15USTRDataLetter.pdf [https://perma.cc/CT26-ZRS4] (recounting the Vietnam catfish food safety issue) [hereinafter Letter from Rosa L. DeLauro]; *see also Froman Says TPP SPS Chapter is Subject to Dispute Settlement, with RMM*, INSIDE U.S. TRADE, Oct. 16, 2015 (arguing that the TPP includes dispute settlement procedures consistent with food and agriculture industry demands).

[2] *See generally* Markus Wagner, *Regulatory Space in International Trade Law and International Investment Law,* 36 U. PA. J. INT'L L., at 1 (2015) (noting that states retain their authority to regulate in policymaking even when joining the WTO and signing international investment treaties) [hereinafter Wagner, *Regulatory Space*]. *See also* Howard Mann, Comment, *The Right of States to Regulate and International Investment Law,* in THE DEVELOPMENT DIMENSION OF FDI: POLICY AND RULEMAKING PERSPECTIVES, at 189 (United Nations Conference on Trade and Development, 2003) (discussing the balance between a state's right to regulate and complying with trade and investment agreements).

[3] For an example of a trade agreement that reaffirms a country's right to regulate, *see Preamble* to TRANS-PACIFIC PARTNERSHIP, *available at* https://ustr.gov/sites/default/files/TPP-Final-Text-Preamble.pdf [https://perma.cc/Y9V2-F5FA] ("Recognize [state's] inherent right to regulate and resolve to preserve the flexibility of the Parties to set legislative and regulatory priorities, safeguard public welfare, and protect legitimate public welfare objectives, such as public health, safety, the environment, the conservation of living or non-living exhaustible natural resources, the integrity and stability of the financial system and public morals"). *See also* Comprehensive Economic and Trade Agreement (CETA), Can.-E.U., art. 8.9, para. 1, *opened for signature* Dec. 2015, http://trade.ec.europa.eu/doclib/docs/2016/february/tradoc_154329.pdf [https://perma.cc/8BQU-36HE] [hereinafter CETA] ("For the purpose of this Chapter, the Parties reaffirm their right to regulate within their territories to

challenging domestic public health regulations illustrates that countries are not afraid to invoke international treaties to reverse domestic law.[4] In an era marked by more agreements and rapidly advancing technologies in food production, new forms of regulatory cooperation are needed to provide countries with sufficient regulatory latitude within a free trade network. An example illustrates this need.

Take for example nanotechnology. The "*Gobstopper*" – a round, brightly-colored, marble-like confectionery made of sugary layers sold in grocery stores in the United States. *Gobstoppers* are coated with submicroscopic particles (nanoparticles), which measure less than 100 nanometers (technology at the scale of atoms and molecules) of *titanium dioxide*,[5] an ingredient commonly added to plas-

achieve legitimate policy objectives, such as the protection of public health, safety, the environment or public morals, social or consumer protection or the promotion and protection of cultural diversity."). The language in the European Union-Vietnam Free Trade Agreement, Article 13 bis, para. 1, is nearly the same. European Union-Vietnam Free Trade Agreement, E.U.-VT, *opened for signature* Feb. 1, 2016, *available at* http://trade.ec.europa.eu/doclib/docs/2016/february/tradoc_154210.pdf [https://perma.cc/S8TG-UWG4].

[4] For an example of a challenge to domestic legislation, see the international investment litigation between Philip Morris International and Australia and Uruguay, respectively. In both cases, the countries defended public health measures and won. In Australia's case (decided 17, December 2015), the investment treaty was a Hong Kong-Australia Bilateral Investment Treaty. Philip Morris Asia, Ltd. v. Australia, Award on Jurisdiction and Admissibility PCA Case Repository No. 2012-12, (Hong Kong Treaty Arbitration Tribunal), http://www.italaw.com/sites/default/files/case-documents/italaw7303_0.pdf [https://perma.cc/7SFB-MEDY]. For a discussion of the genesis of this case, see Wagner, *Regulatory Space*, *supra* note 2, at 6 – 7.

In Uruguay's case, decided in July, 2016 the investment treaty was a Uruguay-Switzerland investment treaty. *Philip Morris Brands Sàrl v. Oriental Republic of Uruguay*, ICSID Case No. ARB/10/7, Award (July 8, 2016), http://www.tobaccofreekids.org/content/press_office/2016/2016_07_08_uruguay.pdf [https://perma.cc/BQ33-YQME].

In 2016, the United Kingdom's High Court upheld its country's plain packaging law, and the European Union's Court of Justice upheld its new tobacco regulations, including a requirement for large, graphic health warnings for EU countries to adopt plain packaging. British American Tobacco et. al v. Dept. of Health (2016), EWHC 1169 (Admin), https://www.judiciary.gov.uk/wp-content/uploads/2016/05/bat-v-doh.judgment.pdf [https://perma.cc/2DCY-XXPP]; Press Release No 48/16, Court of Justice of the European Union, The new EU directive on tobacco products is valid (May 4, 2016), http://curia.europa.eu/jcms/upload/docs/application/pdf/2016-05/cp160048en.pdf [https://perma.cc/7DEG-N68X].

[5] *See* Ravi Ravichandran, *Nanotechnology Applications in Food and Food Processing: Innovative Green Approaches, Opportunities and Uncertainties for Global Market*, INTERNATIONAL JOURNAL OF GREEN NANOTECHNOLOGY: PHYSICS AND CHEMISTRY,

tics, paint, cosmetics and sunscreen, and is also a food additive used in hundreds of foods[6] to whiten or brighten color.[7] And because it contains nanoparticles of this approved food additive, a *Gobstopper* can be considered a nanofood.[8]

Countries are racing to regulate nanotechnology. While in the U.S., nanofoods are Food and Drug Administration (FDA)-approved and generally recognized as safe,[9] other countries limit nanotechnology in foods due to concerns that ingested nanoparticles are so small that they may interact with cells or behave differently than their larger counterparts.[10] The European Union has approved nanotechnology ingredients but requires labeling,[11] a

Vol 1:2, 72, 85 (2010) (noting other nanoparticle used in foods, such as: silicon dioxide, iron oxide, silver, gold, and aluminum).

[6] *See generally* World Health Organization, *FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications, Food and Agriculture Association of the United Nations and World Health Organization, Meeting Report* (2010), http://www.evira.fi/attachments/elintarvikkeet/elintarviketietoa/fao_who_nano_expert_meeting_report_final__2_.pdf [https://perma.cc/56ZQ-KZUM] [hereinafter *FAO/WHO Expert Meeting*].

[7] *Id*. FAO Report, Appendix 4 (listing "current and projected nanotechnology applications in the food and agriculture sectors" in FAO study). *See also* Susan Gaidos, *Noshing on Nano: The tiny particles in what we eat raise big questions*, 188 SCI. NEWS 18 (Oct. 31, 2015), https://www.sciencenews.org/article/nanoparticles-foods-raise-safety-questions [https://perma.cc/D4F9-YHK6] (explaining that "titanium dioxide nanoparticles are frequently added to foods to whiten or brighten color."). *See generally* David Julian McClements, *Nanoscale Nutrient Delivery Systems for Food Applications: Improving Bioactive Dispersibility, Stability and Bioavailability*, 180 J. FOOD SCI. 80, N1602 (July 2015) (discussing the use of nanotechnology in food production).

[8] *See Gaidos*, *supra* note 7, at 18 (noting that the Gobstopper candy includes submicroscopic particles of titanium dioxide, a food additive).

[9] U.S. FOOD & DRUG ADMIN., SUMMARY OF COLOR ADDITIVES FOR USE IN THE UNITED STATES IN FOODS, DRUGS, COSMETICS, AND MEDICAL DEVICES (2015) [https://perma.cc/7SE9-76HD] [hereinafter FDA, SUMMARY OF COLOR ADDITIVES].

[10] *Id*. at 19 (including a list of approved color additive for use in food, drugs, cosmetics, and medical devices).

[11] *See generally* CHRISTIAN HÄBERLI, WORLD TRADE INSTITUTE, A Transatlantic Trade and Investment Partnership Agreement: Implications for Swiss Agriculture, at 15, http://www.nccr-trade.org/fileadmin/user_upload/nccr-trade.ch/wp5/publications/Haeberli_TTIP_Implications_for_Swiss_Agriculture.pdf [https://perma.cc/N4E4-DGUH] [hereinafter Haberli, *Implications for Swiss Agriculture*]. For the U.S. nanotechnology requirements, *see* U.S. FOOD & DRUG ADMIN., NANOTECHNOLOGY (2009) (noting that the FDA regulates products, not technologies).

In the United States, the US Food and Drug Administration (FDA) require manufacturers to demonstrate that the food ingredients and food products are not harmful to health. Yet this regulation does not specifically cover nanoparticles,

move which ultimately limits *Gobstopper* exports and can be perceived as a trade barrier.

The problem is that ultimately these disparate regulatory approaches may lead to a trade-related dispute because traditional forms of international regulatory cooperation (IRC) have difficulty resolving disputes related to new food technologies.[12] Generally, IRC is made up of arrangements (e.g., provisions in trade agreements, international organizations, and standards) like the World Trade Organization (WTO), that "promote cooperation in the design, monitoring, enforcement, and management of regulation to support consistent rules among Members."[13] But the WTO relies upon international organizations to set standards for new technologies and, as is the case with many new technologies, no international standards are available for nanofoods.[14] In addition, political and philosophical tensions often related to new technologies

which could become harmful only in nanosized applications. Thus no special regulations exist for the use of nanotechnology in the food industry.

[12] For instance, if two countries bring a claim to the WTO, the country violating the WTO rule may decide to continue to violate the trade rule and merely pay a penalty. The issue remains unresolved. *See* Memorandum of Understanding, *European Communities - Measures Concerning Meat and Meat Products (Hormones),* WT/DS26/28 (Sep. 30, 2009), http://trade.ec.europa.eu/doclib/docs/2009/november/tradoc_145411.pdf [https://perma.cc/M6QY-MJYE] [hereinafter EU-Meat Products] (listing an example of such a dispute).

[13] *See* Jeffrey L. Dunoff, *Mapping A Hidden World of International Regulatory Cooperation,* 78 L. & CONTEMP. PROBS., 267 (2015) [hereinafter Dunoff, *Mapping a Hidden World*]. *See also* Céline Kauffmann & Nikolai Malyshev, Think Piece, *International Regulatory Co-operation: The Menu of Approaches*, OECD E15 Task Force on Regulatory Systems Coherence at 1 (Oct. 2015), http://e15initiative.org/wp-content/uploads/2015/09/E15-Regulatory-Kauffmann-and-Malyshev-final.pdf [https://perma.cc/KM8K-6XQV] (explaining that "governments use and combine a broad range of formal and informal, broad and specific mechanisms to achieve their co-operation objectives" regarding economic regulation) [hereinafter Kauffman & Malyshev, *International Regulatory Cooperation*].

[14] *See* Steve Suppan, *Racing Ahead: U.S. Agri-nanotechnology in the Absence of Regulation,* INST. FOR AGRIC. & TRADE POL'Y at 4 (June 2011), http://www.iatp.org/files/2011.6.29%20AgriNanotech%20SS.pdf [https://perma.cc/PG45-YSYR] (noting, in July of 2011 that the Codex Commission, the international food–setting organization, may consider whether or not to include nanotechnology in its strategic plan for 2013-2018); FAO/WHO Expert Report, *supra* note 6, at 88 (showing that the current Codex plan does not include nanotechnology). *See also* WORLD HEALTH ORGANIZATION, Strategic Plan 2014 – 2019, ftp://ftp.fao.org/codex/Publications/StrategicFrame/Strategic_plan_2014_2019_EN.pdf (stating that it will address emerging food safety and nutrition issues to include scientific and technological innovation which may include nanotechnology).

prevent adequate dispute resolution.[15] The slow pace of global standard-setting in this area and the inability of the WTO to resolve these issues, signals a need for a 'right to regulate cooperatively'—or a right to access new mechanisms for regulatory cooperation.

This Article argues that, when it comes to food safety, the harms caused by regulatory pluralism outweigh the benefits.[16] The *Gobstopper* example, and others, illustrate that the need for more harmonization of standards, guidelines, and processes is driven by foods perceived as risks,[17] intensifying regulatory differences with

[15] In a hypothetical WTO Claim, the United States would argue that the regulation (or 'trade measure' in the WTO) violates a relevant WTO agreement. The ban could be upheld by a WTO Panel if justified using scientific evidence and if no international standard on nanofoods exists. Two long standing unresolved WTO disputes are EU-Bananas and EU-Hormones. *See* Commission Regulation, No. 2257/94 (Sept. 16, 1994) (laying down the Quality Standards for Bananas within the European Communities). *See also EU-Meat Products, supra* note 12, at 1 (presenting a memorandum of understanding between the US and EU on meat quality). *See e.g.* THOMAS HALE, DAVID HELD & KEVIN YOUNG, GRIDLOCK: WHY GLOBAL COOPERATION IS FAILING WHEN WE NEED IT MOST (2013) (arguing that treaties and other forms of legal cooperation are increasingly inadequate).

[16] For an argument based on benefits, *see* Kauffmann & Malyshev, *International Regulatory Cooperation, supra* note 13, at 1 – 4 (noting "divergences threaten coordinated policy action, hamper interoperability, and raise… costs for businesses and citizens", versus the benefits, including increased trade, investment and GDP, "administrative efficiency gains and cost savings for government, business and citizens" and "societal benefits such as improved safety" and environmental sustainability.). *See also* ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD), INTERNATIONAL REGULATORY CO-OPERATION: ADDRESSING GLOBAL CHALLENGES 15 (2013) (noting that the single largest obstacle to enhanced international trade is the persistence of disparities between nations' regulations); Benjamin M. Weadon, *International Regulatory Arbitrage Resulting from Dodd-Frank Derivatives Regulation,* 16 N.C. BANKING INST. 249, 251, 259 (2012) (noting that lack of international harmonization creates the possibility of regulatory arbitrage) [hereinafter Weadon, International Regulatory Arbitrage]. For an argument based on costs, *see* Annelise Riles, *Managing Regulatory Arbitrage: A Conflict of Laws Approach*, 47 CORNELL INT'L L.J. 63, 83 (2014) (noting a benefit of regulatory pluralism for global financial markets is scope of available regulatory actions); *Managing Regulatory Arbitrage: A Conflict of Laws Approach*, at 77 – 83 (arguing that that there are no common global rules for financial regulation to combat financial arbitrage and even if there were, national governments would not be willing to adopt those rules).

[17] *See* Larry Keener, Sophia Nicholson-Keener, & Tatiana Koutchma, *Harmonization of Legislation and Regulations to Achieve Food Safety: US and Canada Perspective*, 94 J. SCI FOOD AGRIC, 1947, 1951-52 (2014) (noting similarities between the United States', Food Safety Modernization Act, and Canada's Safe Food For Canadian's Act, and noting that nearly half of the foodborne illness outbreaks reported in the United States between 2009-2010 were associated with imported food, implicating foods imported from areas which previously had not been associated with outbreaks).

regard to emerging technologies in food production,[18] differences in regulatory approaches, and WTO disputes, both current and imminent.

New agreements are emerging to provide stronger commitments to IRC in an effort to reduce current and future regulatory differences.[19] In 2012, President Obama issued an Executive Order prompting U.S. federal agencies to engage in IRC[20] by asking them to identify regulations that are likely to have significant international impact and to consider the regulatory frameworks adopted by foreign governments in appropriate circumstances.[21] Under the Executive Order, Obama championed two new IRC initiatives or Mega-Regionals: the Transatlantic Trade and Investment Partnership (TTIP)—between the United States and the European Union—and the Trans-Pacific Partnership (TPP), a 12-nation pact between the United States, Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam.[22]

Mega-Regionals are deep-integration partnerships between countries or regions with a major share of world trade and foreign direct investment, in which two or more of the parties are hubs in global value chains.[23] This new type of agreement, tossed into the "spaghetti bowl"[24] of already existing trade agreements[25] is a de-

[18] *See EU-Meat Products, supra* note 12, at 1 (discussing the importation of meat products treated with hormones and the increased duties on importers).

[19] *See* Haberli, *Implications for Swiss Agriculture*, *supra* note 11, at 4 (explaining that "the most far-reaching objective—and this is where TTIP innovates in respect of any other RTA—was finding a common road map committing the TTIP Parties to solve even future regulatory differences.").

[20] Exec. Order No. 13,609, 77 Fed. Reg. 26,413 – 26,415 (May 1, 2012) (E.O. 13,609 is overseen by the Office of Management and Budget and directs agencies subject to presidential regulatory review to summarize their international regulatory cooperation activities in their Regulatory Plans and to minimize unnecessary differences between U.S. regulatory requirements and those of key trading partners both in promulgating future rules and in conducting retrospective review of existing rules).

[21] *Id.*

[22] Other Mega-Regionals being negotiated are: Transatlantic Trade and Investment Partnership (TTIP), the 16-member Regional Comprehensive Economic Partnership (RCEP) and the 24-member Trade in Services Agreement (TISA).

[23] WORLD ECONOMIC FORUM, MEGA-REGIONAL TRADE AGREEMENTS: GAME-CHANGERS OR COSTLY DISTRACTIONS FOR THE WORLD TRADING SYSTEM? 8 (July 2014), http://www3.weforum.org/docs/GAC/2014/WEF_GAC_TradeFDI_MegaRegionalTradeAgreements_Report_2014.pdf [https://perma.cc/KL5B-2GG5].

[24] The term was first used by Jagdish Bhagwati in *U.S. Trade Policy: The Infat-*

parture from other agreements in that they involve a range of subjects and an ambitious scope, going beyond reductions in tariffs, to address other trade barriers.

This Article focuses on the TPP, an agreement slated to amass one third of world trade,[26] prioritize regulatory cooperation,[27] set higher standards than those found in other trade agreements,[28] and raise the value of trade among its signatories by 2025.[29] This Arti-

uation with Free Trade Areas. Jagdish Bhagwati, *U.S. Trade Policy: The Infatuation with Free Trade Areas*, *in* Jagdish Bhagwati and Anne O. Krueger, THE DANGEROUS DRIFT TO PREFERENTIAL TRADE AGREEMENTS, 1 (AEI Press, 1995).

[25] *See* Ricardo Melendez-Ortiz, *Mega-regionals: What is going on? in Mega-Regional Trade Agreements: Game-Changers or Costly Distractions for the World Trading System?*, WORLD ECON. F. at 13, (July 2014) http://www3.weforum.org/docs/GAC/2014/WEF_GAC_TradeFDI_MegaRegionalTradeAgreements_Report_2014.pdf [https://perma.cc/9GSA-2N62] (last accessed 10/15/16). Examples are the 160-Member World Trade Organization, 432 Regional Trade Agreements (238 of which are in force), and 3,196 International Investment Agreements (IIAs) which include BITS and other IIAs.

[26] *See* IAN FERGUSSEN, MARK MINIMY, & BROCK WILLIAMS, CONGRESSIONAL RESEARCH SERVICE REPORT 42694, THE TRANS-PACIFIC PARTNERSHIP (TPP) NEGOTIATIONS AND ISSUES FOR CONGRESS at 5 (Mar. 20, 2015), https://www.fas.org/sgp/crs/row/R42694.pdf [https://perma.cc/SL7K-S5CJ] ("Economically, TPP would bind together a group that represents 40 percent of global GDP and about a third of world trade").

[27] Trans-Pacific Partnership (released on Nov. 12, 2015), https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text [https://perma.cc/D52Q-JN56]. *See also European Union Ambassador Says Eventual Transatlantic Trade and Investment Partnership (TTIP) Will be Tough to Pass*, INSIDE U.S. TRADE, Oct. 30, 2015 (discussing obstacles to adopting free trade deals). *See EU Ambassador Says Eventual TTIP Deal will be Tough to Pass, Sees CETA as Test Case*, INSIDE U.S. TRADE, Oct. 30, 2015, at 1 (explaining EU Ambassador David O'Sullivan's statements, that the TTIP, once reached, will face a tougher battle to passage than previous free trade agreements in the EU because of the false notion that the TTIP will "force EU governments to give up their authority to regulate").

[28] For some member-nations, standards will be much higher while for others, they will be only slightly higher, varying by industry. This paper argues that food safety standards will be higher for all TPP members. *Contra* Dan Stanton, *TPP Five years data protection for Biologics in the US-Asia Trade Deal*, (Oct. 5, 2015), http://www.biopharma-reporter.com/Markets-Regulations/TPP-Five-years-data-protection-for-biologics-in-US-Asia-trade-deal [https://perma.cc/686S-USNS] (discussing the TPP biologics debate. Noting that in the U.S. biologic pharmaceuticals receive 12 years of patent protection while in some TPP member nations there is no protection. In the end, the bargained-for number of years of TPP protection is 5 [not the highest (12), nor the lowest (0)]).

[29] *See* Global Trade Analysis Project, Purdue University, GTAP Resource Report #4118, https://www.gtap.agecon.purdue.edu/resources/res_display.asp?RecordID=4118 [https://perma.cc/A5Q5-T3L7] (quantifying the economic effects of the proposed TPP by using the GTAP model with the GTAP v8 2007 database, updated to 2014). Here, two scenarios were modeled between 2014 and 2025—the assumed implementation period for the TPP. The "baseline scenario" simulates

cle explains that, obscured by criticism of the TPP,[30] compared to prior trade agreements, the TPP develops a novel framework that promises to integrate domestic regulatory oversight and free trade goals.

Since Mega-Regionals are a new feature to the international economic system, the current literature fails to account for the role that these new agreements can play as drivers for regulatory cooperation and food safety. This Article argues that new agreements carry forward the successes of prior agreements and the ability to urge cooperation to raise global food safety standards. It extends my previous work on food safety governance by arguing that Mega-Regionals have the potential to encourage greater food safety.[31] And, it supports the prevailing wisdom in policy debates and academic literature that problems related to regulatory differences can be counteracted with measures (such as TPP provisions and conflict avoidance mechanisms) to harmonize rules across all legal systems.[32]

This Article specifically examines how food law concerns can be incorporated into the current international regulatory regime, and calls for a new model or regulatory cooperation via Mega-Regional trade frameworks along the lines of the TPP. In so doing, this Article seeks to extend the existing literature on global food

projected growth in GDP and endowments, changes in diets, and the implementation of preferential and unilateral tariff reforms already committed to in the region. A "TPP" scenario adds a hypothetical, full elimination of intra-TPP tariffs and tariff-rate quotas to the network of trade agreements. Results show that the U.S. will supply one-third of the expansion in intraregional agricultural exports—U.S. agricultural exports to TPP partners in 2025 is estimated to be 5% ($2.8 bil.) higher in 2025 due to the TPP. Japan will account for 70% of growth in intraregional agricultural imports—the value of its agricultural imports from its TPP partners in 2025 is expected to be 14% ($5.8 bil.) higher than the baseline.

30 *See* Dan Ciuriak & Harsha Vadhana Singh, Think Piece, *Mega-Regionals and the Regulation of Trade: Implications for Industrial Policy,* E15 Expert Group on Reinvigorating Manufacturing: New Industrial Policy and the Trade System Think Piece, WORLD ECON. F., at 6, 9, (Mar. 10, 2015), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2576887 [https://perma.cc/948F-W9NU] (discussing how criticisms related to transparency, participation, and regulatory impact, are assessments that advantage business groups or countries with greater resources).

31 *See* Alexia Brunet Marks, *A New Governance Recipe for Food Safety Regulation,* 47 LOY. U. CHI. L.J. 3, 907 (2016) [hereinafter Brunet Marks, *Recipe for Food Safety*] (comparing food safety protections in the WTO Agreements with those found in other Bilateral and Regional Trade Agreements, and standards found in the private sector. Mega-Regionals are new treaty agreements which provide higher food safety protections compared to other agreements, short of private standards).

32 *See* Weadon, *International Regulatory Arbitrage*, *supra* note 16 (noting that lack of international harmonization creates the possibility of regulatory arbitrage).

safety[33] and international regulatory cooperation,[34] and contribute

[33] *See e.g.* Ching-Fu Lin, *SPS-Plus and Bilateral Treaty Network: A 'Global' Solution to the Global Food Safety Problem?* 29 WIS. INT'L L.J. 694 (2012) (discussing and offering recommendations on the role of multilateralism and bilateralism in tackling global food-safety problems); Ching-Fu Lin, *Global Food Safety: Exploring Key Elements for an International Regulatory Strategy*, 51 VA. J. INT'L. 637, 637 (2010) (analyzing "the nature of the global food safety crisis against the background of economic globalization and the growing threat of foodborne diseases."); *see also* Stephanie Tai, *Food Systems Law from Farm to Fork and Beyond,* 45 SETON HALL L. REV. 109, 110 (2015) (discussing the "systems-oriented" approach to food policy); Tetty Havinga, *Private Regulation of Food Safety by Supermarkets*, 28 LAW & POL'Y 515, 515 – 533 (2006) (discussing the case study of a Dutch retailer to show how market power can be used to force changes in food policy); Elizabeth Trujillo, Draft, NEW VISIONS FOR TRADE AND SUSTAINABLE DEVELOPMENT, (Monograph), Cambridge University Press (forthcoming, 2017), copy with author; Alberto Alemanno, *The Shaping of European Risk Regulation by Community Courts* (Jean Monnet, Working Paper 18/08, 2008) at 2, http://www.jeanmonnetprogram.org/papers/08/081801.html [https://perma.cc/B5VH-M5B9] (discussing the "main distinctive attributes of the emerging European risk regulatory model."); Alberto Alemanno, *The Multilateral Governance Framework for Food Safety: A Critical and Normative Overview* 9-45, *in* FOOD SAFETY, MARKET ORGANIZATION, TRADE AND DEVELOPMENT (Abdelhakim Hammoudi et al. eds., Springer Publishers: New York 2015) (providing a systematic analysis of the multilateral governance framework for food safety and commenting on areas of fragmentation); Alexia Brunet Marks, *The Risks We Are Willing to Eat: Food Imports and Safety, 52* HARV. J. ON LEGIS. 125 (2015) (arguing that the Food Safety Modernization Act's efforts to increase food safety will be undercut by the growing complexity of international trade); Brunet Marks, *Governance Recipe for Food Safety*, *supra* note 31 (discussing the new system of private standards for food safety and its accompanying short comings).

[34] *See e.g.* Reeve T. Bull, *Developing a Domestic Framework for International Regulatory Cooperation*, 78 LAW & CONTEMP. PROBS. 49, 51 (2015) (proposing a framework for "scrutinizing existing U.S. regulations and eliminating unnecessary international disparities in an effort to encourage regulatory convergence.") [hereinafter Bull]; Ching-Wen Hsueh, *A Greener Trade Agreement: Approaches to Environmental Issues in the TPP Negotiations* 8 ASIAN J. WTO & INT'L HEALTH L & POL'Y 521 (2013) (discussing the environmental impact of TPP adoption and the efficacy of the enforcement mechanism); C. Boyden Gray, *Upgrading Existing Regulatory Mechanisms for Transatlantic Regulatory Cooperation* 78 LAW & CONTEMP. PROBS. 31, 32 (2015) (suggesting means by which progress on "regulatory cooperation under imperfect political circumstance" can be achieved."); Jonathan B. Wiener & Alberto Alemanno, *The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory*, 78 LAW & CONTEMP. PROBS. 103 (2015) [https://perma.cc/A33Y-S2GP] (discussing international regulatory cooperation systems variations and the lessons that can be learned from them); Reeve T. Bull et al., *New Approaches to International Regulatory Cooperation: The Challenge of TTIP, TPP, and Mega-Regional Trade Agreements*, 78 LAW & CONTEMP. PROBS. 1 (2015) [hereinafter Bull et. al. *New Approaches*] (discussing governance, incentives, and obstacles facing the growth of international regulatory cooperation); Dunoff, *Mapping a Hidden World, supra* note 13 (presenting a general survey of international regulatory cooperation); Terence C. Halliday & Greg Shaffer eds., TRANSNATIONAL LEGAL ORDERS, 5 (Oxford University Press, 2015) (noting that IRC activity among

to the ongoing discussion on the right to regulate.[35] It also contributes generally to the academic literatures on global administrative law[36] and the emerging literature on global organizational ecology.[37]

different institutional organizations); Kal Raustiala, *The Architecture of International Cooperation: Transgovernmental Networks and the Future of International Law*, 43 VA. J. INT'L L. 1 (2002) (discussing the decline of liberal internationalist organization for international regulatory cooperation, and the growth of the adaptable and decentralized network model for IRC); Claire R. Kelly, *Institutional Alliances and Derivative Legitimacy*, 29 MICH. J. INT'L L. 605 (2008) (discussing the means by which institutional organizations gain legitimacy and its effect on member states).

[35] This discussion is found within the nascent field comparing international investment and international trade law. *See e.g.* Wagner, *Regulatory Space*, *supra* note 2, at 15 (discussing the level of regulatory autonomy possessed by states in the international investment and international trade regimes); Howard Mann, *The Right of States to Regulation and International Investment Law: A Comment*, in THE DEVELOPMENT DIMENSION OF FDI: POLICY AND RULEMAKING PERSPECTIVES (United Nations Conference on Trade and Development, 2003) at 211 – 225, http://unctad.org/en/Docs/iteiia20034_en.pdf [https://perma.cc/YFP2-TS3Z] (arguing that "reshaping of the purpose of investment agreements from protecting foreign investors to creating investment agreements for sustainable development" properly respects a state's right to regulate); Joel Trachtman, *FDI and the Right to Regulate: Lessons from Trade Law,* in THE DEVELOPMENT DIMENSION OF FDI: POLICY AND RULEMAKING PERSPECTIVE (United Nations Conference on Trade and Development 2003), at 189 – 205, http://unctad.org/en/Docs/iteiia20034_en.pdf [https://perma.cc/YFP2-TS3Z] (analyzing international trade law interaction with domestic law, and applying the insights to international investment law); M. Sornarajan, *Right to Regulate and Safeguards*, in THE DEVELOPMENT DIMENSION OF FDI: POLICY AND RULEMAKING PERSPECTIVES, (United Nations Conference on Trade and Development, 2003), at 205 – 211, http://unctad.org/en/Docs/iteiia20034_en.pdf [https://perma.cc/YFP2-TS3Z] (analyzing international investment agreements for the loss of sovereignty and the related exceptions that follow from joining); Stephan W. Schill, *W(h)ither Fragmentation? On the Literature and Sociology of International Investment Law*, 22 EUR. J. INT'L L. 875, 885 (2011) (summarizing the existing literature on international investment law and its changing nature).

[36] *See* Benedict Kingsbury, Nico Krisch and Richard B. Stewart, *The Emergence of Global Administrative Law*, 68 LAW & CONTEMP. PROBS. 15 (2004) (discussing the shift in focus in literature on international investment law due to changing sociological conditions).

The global administrative law writings usefully address interactions among international organizations, but do not fully address the regulatory interactions among regulators.

[37] *See e.g.* Greg Shaffer, *Transnational Legal Process and State Change: Opportunities and Constraints*, LAW AND SOCIETY INQUIRY (2011) (providing an analysis of the migration of transnational legal norms); Greg Shaffer and Terrence C. Halliday eds., TRANSNATIONAL LEGAL ORDERS, (2015), (defining transnational legal processes and measuring their effects and limits); Friedrich A. Hayek, THE COUNTER-REVOLUTION OF SCIENCE: STUDIES ON THE ABUSE OF REASON (1952) (noting that public regulation is always one step behind the private market); *see also* Abraham L. Newman & David Zaring, *Regulatory Networks: Power, Legitimacy and Compliance,* in INTERDISCIPLINARY PERSPECTIVES ON INTERNATIONAL LAW AND INTERNATIONAL

The analysis proceeds in four parts, followed by a conclusion. Part II defines international regulatory cooperation and makes the case for more regulatory cooperation focusing on food safety and other factors. Parts III and IV describe the problem and provide the solution—a conceptual framework for regulatory cooperation using the TPP as an example. Part V shows how mechanisms aimed at regulatory cooperation may create externalities. Part VI concludes.

2. A GROWING DEMAND FOR MORE REGULATORY COOPERATION

The following describes IRC and identifies the need for more cooperation in global food safety as driven by: (1) the rising threat of foodborne illness and food safety; (2) different regulatory philosophies creating tension within international trade; (3) regulatory "collisions" (take for example a WTO dispute)[38], and (4) 'imminent' regulatory collisions.

2.1. Defining International Regulatory Cooperation

International Regulatory Cooperation (IRC) originated during the postwar era and operates today through a framework of international organizations and treaties addressing different fields. Broadly speaking, IRC involves domestic officials from different jurisdictions interacting to jointly address issues of mutual concern.[39] Examples include the United Nations Declaration on Human Rights and, in the economic realm, the General Agreement on Tariffs and Trade (GATT).[40] While there are several academic articles which provide a typology of IRC,[41] it embraces harmonization,

RELATIONS: THE STATE OF THE ART at 244 (Jeffrey L. Dunoff & Mark A. Pollack eds., 2013) (reviewing scholarship on regulatory networks).

[38] *See EC-Measures Concerning Meat and Meat Products*, *supra* note 12 (providing a Memorandum of Understanding for the importation of beef into the European Community).

[39] *See* Dunoff, *Mapping a Hidden World*, *supra* note 13 at 268 (stating that since the focus is on interactions among domestic regulators, this does not include other important forms of international regulatory cooperation such as interactions among actors from different international organizations and private regimes).

[40] *Id.* at 271 – 73 (a historical perspective on the origins of IRC).

[41] *Id.* at 273 – 74 (discussing the typology of IRC aggreements). *See also,*

"a process in which diverse elements are combined or adapted to each other so as to form a coherent whole while retaining their individuality".[42] Professors Jagdish Bhagwati and the late Robert Hudec wrote extensively on the general characteristics of harmonization as a way to pool regulators' resources in developing standards for public health protection, reducing industry compliance costs in the global market, and minimizing impediments to bringing safe food to consumers.[43] The following discussion provides examples of countries cooperating in ways that harmonize regulatory differences, focusing on food safety.

Countries engage in IRC through several techniques along a continuum, from fully uncoordinated regulatory heterogeneity to fully uniform regulatory homogeneity (convergence).[44] Cooperative regulation can involve a country engaging in any of a number of techniques to reduce regulatory differences.[45] The vehicle for using the technique can be a free trade agreement, international agreement, a standard-setting organization in a specific area, bilateral cooperation among domestic regulators, an international organization, or a Mega-Regional.[46] While countries adopt IRC techniques to achieve certain objectives, I focus on achieving higher levels of food safety. The techniques described below are useful for mapping the prevailing food safety goals and for illustrating how Mega-Regionals expand IRC.

Moving from fully uncoordinated regulatory heterogeneity, countries initiate regulatory cooperation through dialogue and procedural soft law, informally exchanging information to foster mutual understanding and cooperation. Examples of these non-

Kauffmann & Malyshev, *International Regulatory Cooperation*, *supra* note 13 at 1 – 3 (providing a typology of the continuum of IRC agreements).

[42] Martin Boodman, *The Myth of Harmonization of Laws,* 39 AM. J. COMP. L. 699, 702 (1991).

[43] *See generally* FAIR TRADE AND HARMONIZATION: PREREQUISITES FOR FREE TRADE? (Jagdish Bhagwati & Robert E. Hudec eds., 1996) (multiple authors discussing harmonization and divergence in the context of labor, immigration, and environmental regulations). *See also* U.S. FOOD & DRUG ADMIN., *About FDA: Overview,* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OfficeofInternationalPrograms/ucm236581.htm) [https://perma.cc/4TWG-WKFN] (last visited Sept. 21, 2016) (stating that the FDA engages in several forms of regulatory harmonization).

[44] *See* Bull et. al. *New Approaches*, *supra* note 34 (summarizing and analyzing the eleven types of IRC mechanisms provided in two OECD papers).

[45] *Id*. at 8.

[46] *Id*. at 8 – 10.

legally binding instruments include OECD guidelines[47] and principles, and *Global Salmserv*, an international organization of laboratories and individuals involved in amplifying Salmonella prevention which, in 2009, changed its name to the *Global Foodborne Infections Network* to better reflect the scope beyond Salmonella.[48]

Standard-setting is the next step along the continuum and it begins with the adoption of private codes (technical standards[49]) by multinational private standards organizations. Examples of private codes are *GFSI*[50] and *GlobalG.A.P*.[51] Countries participate in international standard setting by relying on private codes or through membership in international organizations.[52] Despite the criticism of the use of international standards,[53] standards are im-

[47] *See* ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, *Guidelines for Multinational Enterprises*, http://www.oecd.org/corporate/mne/ [https://perma.cc/E7PG-94RW] (last visited Sept. 21, 2016) (providing links to different OECD guidelines).

[48] *See* WORLD HEALTH ORGANIZATION, *The Global Foodborne Infectious Network Key Activities*, http://www.who.int/gfn/activities/en/ [https://perma.cc/928F-6735] (last visited Sept. 21, 2016) (describing the major activities of the Global Foodborne Infections Network) [hereinafter WHO, *Global Foodborne Network*].

[49] *See* ALAN O. SYKES, PRODUCT STANDARDS FOR INTERNATIONALLY INTEGRATED GOODS MARKETS at 2 (1995) (defining a product standard as "a specification or set of specifications that relates to some characteristic of a product or its manufacture.").

[50] *See* GLOBAL FOOD SAFETY INITIATIVE, *What is GFSI*, http://www.mygfsi.com/about-us/about-gfsi/what-is-gfsi.html [https://perma.cc/9UEJ-ZVUU] (last visited Sept. 21, 2016) (describing the Global Food Safety Initiative's mission, objectives, and background).

[51] *See* GLOBALG.A.P, *GLOBALG.A.P. - Putting Food Safety and Sustainability on the Map*, http://www.mygfsi.com/about-us/about-gfsi/what-is-gfsi.html [https://perma.cc/7PBZ-T6DT] (last visited Sept. 21, 2016) (providing information about G.A.P and GlobalG.A.P.).

[52] *See* Eibe Riedel, *Standards and Sources: Farewell to the Exclusivity of the Sources Triad in International Law?* 2 EUR. J. OF INT'L L. 58, 81 – 82 (1991) (showing that organizations set standards to harmonize transactions in fields such as environmental law and human rights).

[53] *See* Alberto Alemanno & Giuseppe Capodieci, *Testing the Limits of Global Food Governance: The Case of Ractopamine*, 3 EUR. J. RISK REG. 400 (2012) (arguing that the use of the drug ractopamine will lead to trade disputes and the weakening of multilateral global food safety governance). *See also* Kuei-Jung Ni, *Does Science Speak Clearly and Fairly in Trade and Food Safety Disputes? The Search for an Optimal Response to WTO Adjudication to Problematic International Standard-Making*, 68 FOOD & DRUG L. J. 97, 97 (2013) (stating that Codex standard setting may be unduly influenced by trade interests); Alberto Alemanno, TRADE IN FOOD: REGULATORY AND JUDICIAL APPROACHES IN THE EU AND THE WTO 262 – 3 (2007) ("WTO members have incentives to make sure that the new standards of Codex, IPPC and OIE find inspiration in their current or future national SPS measures," meaning that policy positions on standards are motivated by self-interest). Also, Codex is incentivized

portant in food safety. For example, standards specify limits for pesticide residue levels on the skin of an apple, or for example, "methods for laboratory testing of beef or milk for artificial growth hormones (or natural components, such as fat content) so that food safety inspections and consumer labels provide reliable and comparable information."[54] Standards are also important because, when used to justify a trade measure, the WTO General Agreement on Tariffs and Trade raises a presumption that such measures are legitimate and not protectionist.[55] An example of incorporation of private codes into national legislative instruments can be found in the United States Food Safety Modernization Act requirement that exporters conducting business with United States importers receive external audits from private entities.[56] Another technique for fostering IRC along the continuum is transgovernmental networking, known as cooperation among agencies or national governments based on frequent interaction without formal treaties. The *Global Foodborne Infections Network* serves as an example.[57]

Formal international agreements are next along the continuum and are a typical avenue for fostering IRC. Mutual Recognition Agreements are treaties in which countries retain different national standards in national regulatory law, but agree to allow market access upon approval by the other jurisdiction's regulatory authority. Bilateral agreements for mutual recognition of national regulatory standards or conformity procedures and other forms of regulatory

by the enforceability of the WTO dispute settlement mechanism in such a way that Codex member states tend to vote in a manner what would advance their trade interests rather than promote food safety. A country that has its standards adopted in the Codex will not have to defend its SPS measures in the WTO. Such a presumption may tempt countries to make frequent use of majority voting at Codex meetings.

[54] *See* Tim Büthe & Walter Mattli, *International Standards and Standard-Setting Bodies, in* THE OXFORD HANDBOOK OF BUSINESS AND GOVERNMENT 440, 440 (David Coen et. al. eds., 2010) (stating the importance of food safety standards).

[55] *See* WTO Agreement on the Application of Sanitary and Phytosanitary Measures, art. 3, 1867 U.N.T.S. 493 [hereinafter SPS Agreement] (establishing standards for food safety and sanitary measures for plants and animals); Agreement on Technical Barriers to Trade, art. 2.4, 1868 U.N.T.S. 120 (establishing standards for regulation in order reduce barriers to trade).

[56] *See* U.S. FOOD & DRUG ADMIN., *FSMA Final Rule on Accredited Third-Party Certification*, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361903.htm [https://perma.cc/GF2D-QNX3] (summarizing the rule on accreditation for third-party certification bodies for food safety).

[57] *See* WHO, *Global Foodborne Network*, *supra* note 48 (describing the Global Foodborne Infections Network).

coordination are called regulatory equivalence determinations.[58] These types of agreements are common for certain foods. Using poultry imports as an example, an import may proceed only if the country willing to export proves that its inspection system, guaranteeing the safety of final products, is equivalent to that of the United States with verification of the applicant's inspection system performed by the United States Department of Agriculture.[59]

Next, international agreements are multilateral treaties that aim to reduce regulatory barriers to trade. The WTO is an example of an international organization that makes countries transpose international trade obligations into domestic law through a multilateral treaty.[60] The United States, for example, has free trade agreements in place with twenty nations,[61] and other agreements which seek to harmonize economic relations. A Memorandum of Understanding (MOU), also known as a "Cooperative Arrangement,"[62] is a formal agreement between the FDA and one or more foreign governments or international partners that describes the willingness and good-faith intentions of FDA and its counterpart(s) to engage in coopera-

[58] *See* Kalypso Nicolaidis & Gregory Shaffer, *Transnational Mutual Recognition Regimes: Governance without Global Government*, 68 L. & CONTEMP. PROBS. 263, 264 (2005) [https://perma.cc/8JBG-93NV] ("Mutual recognition forms an essential part of any global administrative law"). For recent case law on equivalence, *see* WTO, *Standards Committee Discusses Tyres, Toy Safety and Food*, https://www.wto.org/english/news_e/news15_e/tbt_10nov15_e.htm [https://perma.cc/SX2J-HALF] (noting that "'equivalence' refers to governments recognizing other countries' measures as acceptable even if they are different from their own, so long as an equivalent level of protection is provided.").

[59] *See* Panel Report, *United States-Certain Measures Affecting Imports of Poultry from China*, ¶2.6, WTO Doc. WT/DS392/R (adopted Sept. 29, 2010), https://www.wto.org/english/tratop_e/dispu_e/392r_e.pdf [https://perma.cc/V5ST-TP6E] (The FSIS, an agency of the USDA, will determine permissibility of importation based on "whether an applicant's poultry inspection system is equivalent to that of the United States").

[60] *See* JARROD WIENER, GLOBALIZATION AND THE HARMONIZATION OF LAW 35 (1999) (noting that harmonization of regulation across borders sometimes occurs through adopting international agreements into domestic law).

[61] *See* OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, *Free Trade Agreements*, https://ustr.gov/trade-agreements/free-trade-agreements (last accessed Sept. 21, 2016) [https://perma.cc/6EPR-G2EC] (listing free trade agreements with Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras, Israel, Jordan, Korea, Mexico, Morocco, Nicaragua, Oman, Panama, Peru, and Singapore).

[62] U.S. FOOD & DRUG ADMIN., *FDA Memoranda of Understanding*, http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/default.htm [https://perma.cc/TP9Y-P568].

tive activities.[63] The FDA enters into MOUs with other entities whenever there is a need to delineate authority or responsibility, or to explain cooperative procedures. A Confidentiality Commitment is a precursor to the Cooperative Arrangement and it allows but does not require countries to share non-public information between governments.[64]

Other agreements enable countries to share resources critical for food safety. The current structure for international/regional foodborne disease surveillance, for example, includes both formal and informal relationships between and among countries. Some examples include the *Global Foodborne Infections Network* and the European Commission Health and Consumer Protection weekly reports from the *Rapid Alert System for Food and Feed* (RASFF).[65] Regulatory agencies in the United States work closely with other countries to assist in developing the U.S. *Foodborne Illness Surveillance System* (FoodNet) in other countries (such as OZFoodNet in Australia).[66] Formal (or informal) coordination with the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations and other international and regional organizations regarding incidents involving intentional contamination is an integral part of strengthening national systems to respond to all food safety emergencies, including country participation in the *INFOSAN Emergency Network*.[67]

Finally, as countries move towards a single regulatory law, countries can promote regulatory cooperation by joining international organizations, such as the Codex Alimetarius Commission

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[63] *Id*.

[64] A 'Confidentiality Commitment' is a document that must be in place for the FDA to share certain non-public information with FDA counterparts in foreign countries and international organizations as part of cooperative law enforcement or regulatory activities.

[65] *See* FOOD AND AGRIC. ORG., *Food Contamination Monitoring and Food-Borne Disease Surveillance at National Level*, http://www.fao.org/docrep/meeting/008/y5871e/y5871e0n.htm [https://perma.cc/F9DU-V8QG] (last visited Sept. 21, 2016) (recommending the establishment of a coordinating body in order to monitor food contamination and conduct foodborne disease surveillance) [hereinafter FAO, *International Cooperation*].

[66] The U.S. agencies which are responsible for forming partnerships with other country regulators include: the U.S. Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (HHS/CDC), the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), as well as the HHS' Food and Drug Administration (FDA).

[67] *See* FAO, *International Cooperation*, *supra* note 65 (describing the objectives of the INFOSAN).

(Codex), the international food standard-setting organization, and entering into formal regulatory partnerships, such as the US-Canada Regulatory Cooperation Council.[68] From there, countries can further harmonize through a supranational or joint regulator or through a formal agreement to adopt the same regulatory standard in each national regulation. An example of this is the United States Food Safety Modernization Act as applied to the United Sates, or European Union Directives as applied to European Union-Member nations. The final step before full cooperation is to enlist a joint regulator, or a single regulatory agency to promulgate joint regulations with standards covering two or more jurisdictions. An example of this is the *Joint Food Standards Australia and New Zealand*.[69]

Among these techniques for food safety, international agreements, mutual recognition agreements, and membership in international organizations are most popular, with the proliferation of private codes and joint regulation gaining momentum. And yet, when harmonization of product standards is neither feasible nor economically viable for some,[70] or when strong preferences of national standards preclude harmonization, recognition of equivalence is an alternative to a specific area, time, degree and scope.[71] In this way, harmonization must be viewed in light of other complementary alternatives discussed below, such as: standard-setting, transparency and monitoring, technical assistance, recognition and equivalence, economic integration, convergence of policy proce-

[68] For a description of the US-Canada Regulatory Cooperation Council, *see* UNITED STATES – CANADA REGULATORY COOPERATION COUNCIL, JOINT FORWARD PLAN, https://www.whitehouse.gov/sites/default/files/omb/oira/irc/us-canada-rcc-joint-forward-plan.pdf (2014) [https://perma.cc/5ZS2-U74L] (last visited Sept. 21, 2016) (describing various initiatives to improve regulatory cooperation).

[69] *Id.*

[70] *See* Dunoff, *Mapping a Hidden World*, *supra* note 13 at 150 (noting that a complementary approach to harmonization is recognition of equivalence, given the substantial challenge that harmonization may be).

[71] *See* William A. Kerr & James D. Gaisford, HANDBOOK ON INTERNATIONAL TRADE POLICY (2007), at 400; David W. Leebron, *Lying Down with Procrustes: An Analysis of Harmonization Claims*, *in* FAIR TRADE AND HARMONIZATION: PREREQUISITES FOR FREE TRADE? 41, 91 (Jagdish Bhagwati & Robert E. Hudec, eds., 1996) (arguing that "mutual recognition achieves most of the benefits of harmonization with few of its costs"). *See also* TIM E. JOSLING, ET AL., FOOD REGULATION AND TRADE: TOWARD A SAFE AND OPEN GLOBAL SYSTEM 194 (Institute for International Economics 2004) (noting that "equivalence is an alternate to harmonization" that has some pros and cons).

dures, or regulatory mechanisms within international legal regimes.[72]

2.2. Food Safety Threats and Challenges

Regulators are keenly aware of the various risks related to food imports that result from mislabeling, undeclared allergens, the use of banned additives, and food contamination.[73] But as advances in food science and food production become more technologically complex, and as supply chains continue to grow, regulators need to minimize food safety risks[74] related to new technologies and new country sources.

A wide range of new technologies is emerging to meet various food production needs. Some technologies make food resistant to disease, grow faster and more efficiently, produce less waste, or help produce novel products that benefit humans. Others make food more attractive (e.g. titanium dioxide in the case of *Gobstoppers*) or increase food safety.[75] For example, the processing method of bathing poultry in antimicrobial baths ("pathogen reduction treatments") commonly uses chlorine and lactic acid to reduce risk of Salmonella. While chlorine baths are now common in the United States (and 120 countries) as a food safety measure to kill bacte-

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[72] *See* CHRISTIAN STRUCK, PRODUCT REGULATIONS AND STANDARDS IN WTO LAW 163 (2014); Dunoff, *Mapping a Hidden World supra* note 13 at 273 (arguing that global regulators lack many regulatory mechanisms that are common features of domestic regulators). *See also* David W. Leebron, *Mutual Recognition: Structure, Problems and Prospects, in* REGULATORY REFORM AND INTERNATIONAL MARKET OPENNESS 205, 213 (1996) (noting that harmonization, standardization and recognition of equivalence serve complementary functions).

[73] *See* Brunet Marks, *The Risks, supra* note 33 (referring to the import refusal dataset).

[74] For a list of risks, see FAO, *International Cooperation*, *supra* note 65 (listing risks such as soil degradation). And, to be sure, the examples of nanofoods and genetically modified foods are stand-ins for a number food-related issues, technologies currently being tested and considered, such as growth hormones, food products from cloned animals, endocrine disrupting chemicals, antimicrobial resistance to antibiotics, plant synthetic biology, and future food risks that public health and safety regulation may address.

[75] *See* Joanna Klein, *Dolly the Sheep's Fellow Clones, Enjoying Their Golden Years,* N.Y. TIMES, Jul. 26, 2016, http://www.nytimes.com/2016/07/27/science/dolly-the-sheep-clones.html?hp&action=click&pgtype=Homepage&clickSource=story-heading&module=second-column-region&region=top-news&WT.nav=top-news&_r=0 [https://perma.cc/QB43-5R8H] (noting that the European Union bans the sale and import of food from cloned animals).

ria, Europe has banned them since 1990 as a possible cancer risk (though Europe allows meat bathed in lactic acid).[76]

As regulators try to develop an acceptable risk management strategy with respect to new technologies, IRC techniques provide regulators with a range of options. International food standards, drafted by the Codex Commission, are frequently used to guide regulation. In 2011, Codex established a standard for washing meat using chlorine or lactic acid.[77] This new standard pressured the European Food Safety Association to consider adopting lactic acid as a washing agent. The European approach (using lactic acid) will not be identical to the approach in the United States (using chlorine), but the regulations will be equivalent in that they accomplish the same end result. Here, an equivalence determination was the IRC technique used to resolve this regulatory difference. What happens in cases such as nanotechnology, where standards do not exist? In this situation, different IRC techniques, starting with dialogue, can be used to encourage cooperation, and some agreements can foster IRC better than others.

With new supply chains, often in new geographical areas, it can be particularly difficult to verify that new suppliers can provide the requisite regulatory framework and sufficiently robust public health measures to ensure the safety of the foods offered for international trade.[78] Some food risks do not involve new technologies but can be traced to longstanding food safety problems, such as fish trade with Asia.

Every year, consumers in the United States purchase two trillion dollars' worth of imported products from 825,000 importers

[76] *See* Susanna Capelouto, *European Activists Say They Don't Want Any U.S. 'Chlorine Chicken'*, NPR, Sept. 30, 2014 http://www.npr.org/sections/thesalt/2014/09/30/351774240/european-activists-say-they-dont-want-any-u-s-chlorine-chicken [https://perma.cc/3DTX-CCGX] (mentioning the ban upon chlorine treated chicken). *See also* Laurence Peter, *TTIP Talks: Food Fights Block EU-US Trade Deal*, BBC NEWS, June 10, 2015, http://www.bbc.com/news/world-europe-33055665 [https://perma.cc/9845-Q3E7] (describing that the EFSA is considering whether to allow peroxyacetic acid as a poultry rinse).

[77] *See* CODEX ALIMENTARIUS COMMISSION, *Report of the Forty-Second Session of the Codex Committee on Food Hygiene*, Appendix 3, ¶77, U.N. Doc. REP 11/FH, http://www.ift.org/public-policy-and-regulations/advocacy/~/media/Public%20Policy/International%20Advocacy/Codex_CCFH.pdf [https://perma.cc/SSJ3-ZE34] (stipulating the guidelines for washing carcasses to prevent salmonella and campylobacter in chicken meat).

[78] *See generally* Brunet Marks, *The Risks*, *supra* note 33 (discussing the challenges and shortcomings facing the Food Safety Modernization Act of 2011, which updates regulatory means for fighting food safety risks).

through more than 300 ports of entry. These numbers are rising[79] making food safety breaches inevitable. The United States imports 80% of its fish supply, largely from developing countries in Asia. United States Center for Disease Control (CDC) experts reviewed outbreaks from 2005-2010 for foods imported to the United States and found that during those years, 39 outbreaks and 2348 illnesses were linked to food imports from 15 countries.[80] Nearly half (17 outbreaks) occurred in 2009 and 2010 with 45% of the imported foods causing the outbreaks coming from Asia.[81] Fish (17 outbreaks) were the most common source of implicated imported foodborne disease, followed by spices (6 outbreaks).[82] These longstanding food safety problems motivate regulators in different countries to work together to harmonize standards and regulatory requirements.

For instance, for some time, United States consumers have complained about lax food safety standards in Vietnam and Malaysia over catfish exports with traces of antibiotics. As complaints heightened during the TPP negotiations[83] the catfish inspections shifted to the USDA from the FDA.[84] In the United States, food is

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[79] *See* Press Release, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), HHS Preparing to Open FDA Offices in China, India, Europe and Latin America This Year (Oct. 16, 2008), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm153679.htm [https://perma.cc/976P-ELW7] (announcing the opening of several international FDA offices).

[80] *See* Press Release, US CENTERS FOR DISEASE CONTROL AND PREVENTION, CDC Research Shows Outbreak Linked to Imported Foods Increasing (Mar. 14, 2012), https://www.cdc.gov/media/releases/2012/p0314_foodborne.html [https://perma.cc/LZ8E-F3ZC] (stating that the increase in outbreaks is related to increased food imports).

[81] *Id.*

[82] *Id.*

[83] *See* Dan Flynn, *House Leaders Asked Not to Vote on Senate Resolution to End USDA Catfish Inspection*, FOOD SAFETY NEWS, (May 31, 2016), http://www.foodsafetynews.com/2016/05/house-might-not-vote-on-senate-maneuver-to-end-usda-catfish-inspection/#.V42eSKJbjsA [https://perma.cc/VM5H-FWT4] (noting that United States Farm Bills going back to 2008 require catfish inspections). *See also* Letter from Rosa L. DeLauro, *supra* note 1 (exemplifying complaints as the TPP was being drafted).

[84] Dan Flynn, *USDA Plans to Begin Catfish Inspections in March 2016*, FOOD SAFETY NEWS, (Nov. 26, 2015), http://www.foodsafetynews.com/2015/11/usdas-domestic-and-foreign-catfish-inspections-will-begin-in-march-2016/#.Vq47Y0ZRoio [https://perma.cc/2SU2-YBB6] (stating that the USDA released a final rule shifting catfish inspections to the Agency from the FDA, under a special program beginning in March, 2016, which will include equivalency determinations and audits). *See also* Press Release, US DEPARTMENT OF AGRICULTURE, USDA Releases Final Rule Establishing Inspection Programs for Siluriformes Fish,

mostly regulated by three agencies: the FDA, USDA and the Environmental Protection Agency. There are problems that come with regulating in tandem,[85] but also advantages– such as being able to fix food safety problems by shifting agency oversight. Compared to the FDA, the USDA has more strict enforcement.[86] While catfish inspection under the USDA may improve, agency shifts are not a long-term sustainable solution.[87] This example shows that regulatory differences in enforcement of domestic food safety regulations (or lack thereof) can motivate more regulatory cooperation (from less stringent FDA oversight to more stringent USDA oversight). The following section shows how varying regulatory approaches, based on differences in philosophy and culture, motivate greater IRC.

2.3. Competing Philosophical Approaches to Regulation

Countries have the right to enact regulations to protect public health and safety and they do so, based on different perceptions of what constitutes a risk. As Trebilcock and Soloway point out, "one nation's bunch of grapes is another nation's repository of carcinogenic pesticide residue."[88] Regulatory differences can emerge from differences in constitutional and political structures,[89] regulatory

Including Catfish (Nov. 25, 2015), http://www.fsis.usda.gov/wps/portal/fsis/newsroom/news-releases-statements-transcripts/news-release-archives-by-year/archive/2015/nr-112515-01 [https://perma.cc/YB5M-R6N9] (providing the final Catfish inspection rule).

[85] *See* Phillip R. Trimble, *A Revisionist View of Customary International Law*, 33 UCLA L. REV. 665, 701 (1986) (noting the friction in foreign relations that results from conflicting national regulation) [hereinafter Trimble].

[86] Border inspections will improve once the FDA Food Safety Modernization Act and the new import safety rules are implemented, but for the time being, low rates of FDA border inspections will continue to compromise the safety of food entering the United States.

[87] Additionally, the TPP rules do not necessitate the enforcement of domestic rules. There is no enforcement mechanism for domestic inspections.

[88] *See* Michael Trebilcock & Julie Soloway, *International. Policy and Domestic Food Safety Regulation: The Case for Substantial Deference by the WTO Settlement Body under the SPS Agreement*, *in* THE POLITICAL ECONOMY OF INTERNATIONAL TRADE at 1 (Daniel L. Kennedy & James D. Southwick eds., 2002).

[89] *See* Richard Parker & Alberto Alemanno, *Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Legislative and Regulatory Systems*, EUROPEAN COMMISSION (2014) http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152466.pdf [https://perma.cc/WT8P-UYUX]

divergences, disparate risk assessments and tolerances, political considerations,[90] historical values, and cultural norms.[91] Regulatory differences can also develop when harmonization presents remarkable practical and political challenges.[92]

Two regulatory paradigms have come to dominate international debates and disputes over health and environmental risk – one based on 'sound science', or the 'reasonable certainty of no harm' standard, and one based on the 'precautionary principle'.[93] While both regulatory approaches are science-based in that scientific evidence is the point for assessments of risk, they diverge on the way scientific evidence is *evaluated* given different sensitivities to uncertainties and levels of emphasis placed on social and economic matters.[94]

The United States' notion of 'sound science' emphasizes that protective actions should be used only when there is sound scientific evidence of risk.[95] Evidence is limited to that 'gathered through scientific methods' with the result that only 'a complete, self-contained, scientific evaluation' will be considered an adequate risk assessment.[96] Meanwhile, the 'precautionary principle',

(showing that U.S., regulatory programs are relatively highly centralized in the federal government with administrative agencies playing a major role in decision making; while in Europe, regulatory authority is shared between the EU and member states).

[90] *See* Bull, *supra* note 34 (offering a detailed view of the four causes of regulatory differences).

[91] *See* DANIEL W. DREZNER, ALL POLITICS IS GLOBAL: EXPLAINING INTERNATIONAL REGULATORY REGIMES at 162 – 64 (2007) (explaining why the European Union agreed to the SPS).

[92] *See* Ravichandran, *supra* note 5, at 77 – 83 (providing an example of how the precautionary principle may take too long compared to equivalence, but equivalence is more politically feasible).

[93] *World HEALTH ORGANIZATION, THE PRECAUTIONARY PRINCIPLE: PROTECTING PUBLIC HEALTH, THE ENVIRONMENT AND THE FUTURE OF OUR CHILDREN* at 94 (Marco Martuzzi and Joel A. Tickner, eds. 2004) [hereinafter *WHO*, THE PRECAUTIONARY PRINCIPLE].

[94] *Id*. at 169.

[95] *See Mills v. Grant of Md. L.L.C.*, 441 F. Supp. 2d 104 (D.C. 2006) (aff'd 508 F.3d 11 (D.C. Cir. 2007) (citing 21 C.F.R. 170 (3i)) ("the FDA has defined 'safety' to mean that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use").

[96] *See* Panel Report, *Japan-Measures Affecting the Importation of Apples*, 8.92, WTO Doc. WT/SD245/R (adopted July 15, 2003), https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds245_e.htm [https://perma.cc/SZ97-5RXH] (providing an example in Japan's restrictions on American apple exports). *See also* Panel Report, *European Communities-Measures Affecting the Approval and Marketing of Biotech Products*, 7/3188. WTO Doc. WT/DS/291/R; WT/DS292/R; WT/DS293/R,

articulated in the 1960s, and widely adopted today, generally advocates for regulating when faced with scientific uncertainty about risk to human health and the environment.[97] This principle acknowledges that scientific understanding is limited and precautionary action can serve underlying values based on what is known as well as what is not known.[98] It encourages close scrutiny of all aspects of science, from the research agenda to the funding, design, interpretation and limits of studies, and involves recognizing that the answer science gives to questions of safety and risk typically depends on the specific question asked, how it is framed, and the underlying assumptions.[99] In practice then, the question becomes whether there is flexibility, where issues of scientific uncertainty arise, to embrace broader forms of risk assessment that blend scientific findings, anecdotal information, and value concerns.[100] Ultimately, a food producer has to demonstrate that a food product is safe: when there are credible threats of harm, precautionary action should be taken, even absent full understanding of the effects of a proposed activity.

While the precautionary principle has application in other countries,[101] the European Union[102] has become a strong proponent

(adopted Sept. 29, 2006), https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm [https://perma.cc/VJ5V-TM6Y] (resolving a dispute over biotechnology products imported into the EC from the United States).

[97] *See* WHO, THE PRECAUTIONARY PRINCIPLE, *supra* note 93, at 7 ("in cases of serious or irreversible threats to the health of humans or ecosystems, acknowledged scientific uncertainty should not be used as a reason to postpone preventive measures").

[98] *Id*. (noting that the precautionary principle carries its own values. The principle is based on recognizing that people have a responsibility to prevent harm and to preserve the natural foundations of life, now and into the future. The needs of future generations of people and other species and the integrity of ecosystems are recognized as being worthy of care and respect. A precautionary approach asks how much harm can be avoided rather than asking how much is acceptable. It acknowledges that the world comprises complex, interrelated systems that are vulnerable to harm from human activities and resistant to full understanding. Precaution gives priority to protecting these vulnerable systems and requires gratitude, empathy, restraint, humility, respect, and compassion).

[99] *Id*. at 194.

[100] *Id*.

[101] The precautionary principle is said to originate in Germany, however, other countries including the U.S. also have a long history of reliance on precautionary approaches to regulation. The United States led with precautionary environmental policies in the 1960's, 70's and 80's. By the 1990s, the roles had reversed, and it was the U.S. government that resisted precautionary-based controls in areas such as climate change, whereas the EU surged ahead. *See* Jonathan B. Weiner, *Whose Precaution After All? A Comment on the Comparison and Evolution of*

of precautionary regulation in a range of health and environmental areas.[103] Beginning with regulatory failures and 'crises' that took place in Europe in the late 1980s (concerning nuclear and chemical accidents) and the latter half of the 1990s (involving food safety and health protection – most prominent of which was mad cow disease, which severely undermined public trust in European Union food safety regulations and the scientific expertise on which they were based),[104] European regulatory policies began to embrace a more stringent approach compared to American regulatory policies.[105] In the Maastricht Treaty in 1992, the European Union expressly provided that the European Union policy on the environment "shall be based on the precautionary principle".[106] Despite its environmental origins in the European Community Treaty, the precautionary principle has shown that it has application in

Risk Regulatory Systems, 13 DUKE J. COMP. INT'L. L. 207 (2003) (comparing US and EU regulations generally). *See also WHO, THE PRECAUTIONARY PRINCIPLE*, *supra* note 93, at 42 (providing an in-depth discussion of the principle).

102 Alberto Alemanno, *The Shaping of European Risk Regulation by Community Courts* (Jean Monnet Working Paper 18/08, 2008), http://www.jeanmonnetprogram.org/papers/08/081801.html [https://perma.cc/U5E4-WCBF].

103 Most notably in climate change, biotechnology, and chemicals regulation. By contrast, it was the USA throughout the 1970s and 1980s that pushed most strongly for precautionary international environmental agreements for endangered species protection and the regulation of ozone-depleting substances.

104 *See* Wiener & Alemanno, *supra* note 34, at 169 (noting the discussion on delegation of authority to regulatory agencies). *See also* David Vogel, *The Politics of Risk Regulation in Europe and the United States*, in 3 THE YEARBOOK OF EUROPEAN ENVIRONMENTAL LAW 1, 2 – 3, 24 – 34 (H. Somsen et al. eds., 2003) (cataloguing various regulatory failures over the course of the 1980s and 1990s in Europe); Wiener, *infra* 106, at 227 (indicating nations that generally take a more 'precautionary' approach than the U.S. in the nuclear power area, because the U.S. experienced the Three Mile Island disaster, while the EU did not have any equivalent meltdown in the EU).

105 David Vogel, *The Hare and the Tortoise Revisited: The New Politics of Consumer and Environmental Regulation in Europe*, 33 BRITISH J. POL. SCI. 557, 571 – 73 (2003).

106 Jonathan B. Wiener, *The Rhetoric of Precaution*, in THE REALITY OF PRECAUTION: COMPARING RISK REGULATION IN THE UNITED STATES AND EUROPE, (Jonathan B. Wiener et al. eds., 2011) (noting that the Treaty on European Union, Official Journal C 191, 29 July 1992 entered into force 1 Nov. 1993. This treaty changed the name of the former European Economic Community to simply the 'European Community' and added new provisions to the Community's constitutive treaty document. The new provisions included Article 130r concerning the role of the precautionary principle in Community environmental policy). *See also*, Treaty of Amsterdam Amending the Treaty on European Union and the Treaties Establishing the European Communities and Related Acts, 1997, O.J. (C 340) (entered into force May 1, 1999) (enacting the precautionary principle in Article 174(2) of the EC Treaty).

other areas, for instance, to protect human health and plant health.[107]

Philosophical differences can become a source of contention when national regulatory approaches come into conflict at the international level.[108] In the late 1990s, precaution began to emerge as the focus of dispute between the European Union, the United States, and other large trading blocs.[109] Two examples illustrate how these two paradigms differ with respect to regulating new food technologies (and where cooperation is needed).

The first example uses *Gobstoppers* to compare how the European Union and the United States regulate nanotechnology. As noted earlier, *Gobstoppers* contain titanium dioxide, a nanoparticle and food additive, used to brighten color. The European Union requires labeling ingredients derived from nanotechnology[110], while the United States does not. In the United States, the FDA regulates food products and not food technologies so no special regulations exist for the use or labeling of nanotechnology in the food industry.[111] As a food additive, titanium dioxide requires FDA approval through a petition process that assures that the additive is safe for its intended use.[112] To date, food ingredients and food products

[107] *Id*. at 52 (citing the European Commission communication on precaution).

[108] *See* Trimble *supra* note 85. There are other problems as countries treat nations as working under one regulatory entity when this is not often the case. Trimble notes the friction in foreign relations that results from conflicting national regulation – which is the case for food safety as it is regulated by several federal agencies.

[109] *See* WHO, THE PRECAUTIONARY PRINCIPLE, *supra* note 93, at 51 (noting that in the 1990s, the EU cited the precautionary principle to justify trade restrictions on the import of United States beef treated with hormones and of genetically modified food material, reasoning that the science was not sufficiently robust. The U.S., meanwhile, claimed that the principle was an unjustified trade barrier).

[110] *See Exec. Order No. 13,609*, *supra* note 20 (noting that the European Union has recommended special regulations that have yet to be accepted and enforced. Also noting that the Royal Society and the Royal Academy of Engineering recommend indicating nanoparticles in the lists of ingredients).

[111] S*ee* Nanotechnology, U.S. FOOD AND DRUG ADMINISTRATION (last updated Aug. 5, 2015), http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm [https://perma.cc/MXW9-Y9LQ] (noting that the FDA says that it regulates "products, not technologies." In the United States, the US Food and Drug Administration (FDA) requires manufacturers to demonstrate that the food ingredients and food products are not harmful to health, yet this regulation does not "specifically" cover nanoparticles, which could become harmful only in nano-sized applications. Thus no special regulations exist for the use of nanotechnology in the food industry).

[112] *See Guidance for Industry: Questions and Answers about the Petition Process*, U.S. FOOD & DRUG ADMINISTRATION (last updated July 1, 2016),

are not harmful to health[113] yet the approval of titanium dioxide as an additive did not specifically cover nanoparticle properties or potential risks.

Another example uses *AquAdvantage Salmon*,[114] a genetically modified salmon developed in the United States, to compare how the European Union and the United States regulate genetically modified food. The United States 'sound science' approach requires the FDA to show that the genetically modified food is as safe as its non-genetically modified counterpart.[115] In 2016, the FDA determined that food from *AquAdvantage Salmon* is as safe to eat as food from non-genetically modified Atlantic salmon and, since there is no "material difference" between the genetically modified Atlantic salmon and the non-genetically modified Atlantic salmon, there is no obligation to label the product as genetically modified (although the FDA will issue guidance to companies on how to label products voluntarily).[116] Yet, despite FDA approval,

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments RegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm253328.htm [https://perma.cc/THK5-K6AH] (providing guidance on the petition process related to food additives).

[113] *See* U.S. FOOD & DRUG ADMINISTRATION, *Summary of Color Additives for Use in the United States in Foods, Drugs, Cosmetics, and Medical Devices* (last updated Nov. 30, 2015), http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm115641.htm [https://perma.cc/ERM8-2HTB] (listing food additives).

[114] Andrew Pollack, *Genetically Engineered Salmon Approved for Consumption*, N.Y. TIMES, (Nov. 19, 2015), http://www.nytimes.com/2015/11/20/business/genetically-engineered-salmon-approved-for-consumption.html [https://perma.cc/7ZGH-2NDU] (noting that an Atlantic salmon contains a growth hormone gene from a Chinook salmon and a fragment of ocean pout DNA that acts as a sort of perpetual "on" switch—a combination that helps the salmon grow large enough for consumption in 18 months instead of the typical three years).

[115] As part of its evaluation, the FDA examined data comparing three groups of fish: non-GE farm-raised Atlantic salmon from both the sponsor's farm and from a different commercial farm, and AquAdvantage Salmon. This study compared key hormones (including estradiol, testosterone, 11-ketotestosterone, T3, T4 and insulin-like growth factor 1) and found no biologically relevant differences. *See* U.S. FOOD & DRUG ADMINISTRATION, *AquAdvantage Salmon Fact Sheet* (last updated Dec. 21, 2015), http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm473238.htm [https://perma.cc/7ZGH-2NDU] (summarizing features of AquAdvantage Salmon).

[116] *See* U.S. FOOD & DRUG ADMINISTRATION, *AquAdantage Salmon* (last updated on Apr. 7, 2016), http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm280853.htm [https://perma.cc/72RE-ZPHN] (listing documents related to the AquAdvantage Salmon approval).

within the United States, certain states and counties have passed bills which require labeling for foods containing genetically modified organisms.[117]

The precautionary principle is now most prominent in European Union law relating to food safety (as seen in the regulation of genetically modified organisms or 'GMOs').[118] The European Union approach requires genetically modified food to undergo a strict approval process for import or sale– so strict that only one genetically modified crop has been approved to date.[119] Genetically modified crops require pre-approval prior to their release , as per the 2001 European Union GMO Directive on the deliberate release into the environment of genetically modified organisms, one of the few European Union environmental risk instruments to be explicitly based on the precautionary principle.[120] In 2015 the rules changed and thus European Union members can now ban cultivation of genetically modified crops on their territory,[121] and 'opt out' imports of genetically engineered food and feed,[122] even when the

[117] *See State Labeling Initiatives*, CENTER FOR FOOD SAFETY (2016), http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/state-labeling-initiatives# [https://perma.cc/U85B-EVFB] (describing state-level GMO labeling initiatives).

[118] *See* Bull, *supra* note 34, at 135 (noting the trend toward regulatory harmonization).

[119] Ned Stafford, *New E.U. Law Lets Nations Ban Gene-Modified Crops*, CHEMISTRY WORLD (Jan. 19, 2015), *reprinted in* SCI. AM. (2016), http://www.scientificamerican.com/article/new-e-u-law-lets-nations-ban-gene-modified-crops/ [https://perma.cc/58WR-Y8NA] (noting the insect resistant maize MON810 is the only GM crop cultivated in the EU, grown mainly in Spain and Portugal. Since MON810 was approved for EU cultivation in 1998, no additional GM grains have won approval, with MON810 cultivation banned in Germany, France, Italy, and other nations, undermining the concept of a single European market).

[120] *See generally* Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, 2001 O.J. (L 106). *See also*, *The EU Regulatory System for GMOs*, in UNCERTAIN RISKS REGULATED 269 (Michelle Everson & Ellen Vos eds., Abingdon: Routledge-Cavendish, 2009) (providing a detailed discussion of Directive 2001/18/EC).

[121] *See Eight Things You Should Know about GMOs*, EUROPEAN PARLIAMENT NEWS, (Oct. 27, 2015), http://www.europarl.europa.eu/news/en/news-room/20151013STO97392/Eight-things-you-should-know-about-GMOs [https://perma.cc/9XN4-MXLS] (stating that under the law, EU nations will be allowed to ban GMOs on the grounds of environmental policy, town and country planning, socio-economic impact, avoiding the unintended presence of GMOs in other products, and on farm policy objectives).

[122] *See* Press Release, Office of the US Trade Representative, USTR Expresses Concern over EU Proposal to Allow Member States to Ban the Use of GE Food

science-based safety and environmental determinations made by the European Union allow the importation and sale of genetically modified crops. [123]

As the two regulatory approaches are debated, other countries look on with interest. In the 1980s and 1990s, interest in the precautionary principle rapidly spread well beyond Europe.[124] To further economic trade, developing countries have had to align with one of the competing regulatory schemes[125] with African nations aligning with the precautionary principle, presumably due to historical ties with Europe. Other factors outside of trade relations help spread the precautionary principle.

Over the last few decades the precautionary principle has become an established element not only of international environmental law, but also the domestic environmental law of a number of countries such as Australia, Canada,[126] and India. Recently, Japan used the precautionary principle to justify a trade measure which restricted apple imports from the United States in order to prevent the introduction of the 'fire blight' plant disease (which affects plants but has no human health consequence).[127] In *Japan-Apples*, the United States challenged Japan's measures in the WTO and Japan defended the restrictions as 'precautionary', arguing for deference to Japanese national authorities in their interpretation of the scientific evidence.[128] The WTO found the measure violated the

and Food Deemed Safe by EU (Apr. 22, 2015), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/april/ustr-expresses-concern-over-eu [https://perma.cc/XG6B-WZGF] (expressing concern about a movement toward regulatory disharmony).

123 *Eight Things You Should Know About GMOs*, *supra* note 121.

124 *See* WHO, THE PRECAUTIONARY PRINCIPLE, *supra* note 93, at 46 (noting the widespread agreement on the precautionary principle).

125 *See e.g.* Morris, *supra* note 4 (noting that this is true of products that both do or do not contain GMOs).

126 Precautionary Principles: Government Positions - Canada, Sci. & Envtl. Health Network, http://www.sehn.org/canada.htmlvv [https://perma.cc/ED74-LFQ6] ("'More than 70 municipalities (including Vancouver, British Columbia; Montreal, Quebec; and Halifax, Nova Scotia) have already passed bylaws prohibiting the cosmetic use of pesticides, and many more cities are poised to pass bans now that the Supreme Court has cleared the way.' Early bans cited the precautionary principle").

127 Panel Report, World Trade Organization, Japan-Measures Affecting the Importation of Apples, WT/DS245/RW (adopted June 23, 2005) [hereinafter *Japan-Apples*].

128 *Id.*

SPS Agreement because it lacked scientific support[129] and was "a disguised restriction on international trade".[130] *Japan-Apples* – while dealing with plant health and not human health – illustrates that the WTO dispute settlement decisions have narrowly interpreted the SPS Agreement to allow for standards set by scientific evidence (against the precautionary principle). Such a narrow perspective could potentially reverse a ban on the importation of *AquAdvantage Salmon* in Europe.[131]

And yet, while over the last few decades the precautionary principle has become an established element in the domestic law of certain countries, some argue that countries oscillate between approaches to regulation based on the target of regulation. Notwithstanding common perceptions concerning greater desire for the precautionary principle in Europe, the reality is that United States regulations are more precautionary than their European counterparts in some areas and less so in other areas (e.g. limitations on carbon emissions are stricter in Europe),[132] while in some areas, the level of precaution is nearly equivalent (e.g. auto safety standards). This has implications on regulatory convergence— where one side is significantly more precautionary than the other, the likelihood of regulatory convergence is limited.[133] The following sections draw upon trade disputes (emerging from philosophical differences or otherwise) to motivate the need for more international regulatory

[129] *Id.*

[130] *See* WTO SPS Agreement, Article 5.5 (and by association Article 2.3), https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm [https://perma.cc/QVU7-3AS2] ("each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade").

[131] *See e.g.* Steve Connor, *Genetically Modified Salmon Becomes First to be Approved for Human Consumption – But it Won't Have to be Labelled as GM*, The Independent (Nov. 19, 2015), http://www.independent.co.uk/news/science/genetically-modified-salmon-becomes-first-to-be-approved-for-human-consumption-but-it-wont-have-to-a6741031.html [https://perma.cc/8UDC-PQZY] ("'There remain legitimate ecological concerns over the possible consequences if GM salmon escape to the wild and reproduce, despite FDA assurances over containment and sterility, neither of which can be guaranteed,' said Joe Perry, former chair the GM panel of the European Food Safety Authority.")

[132] Reeve Bull, *Answering TTIP's Critics: Regulatory Cooperation in Risk Assessment and Risk Management* (Dec. 2, 2016), https://regulatorystudies.columbian.gwu.edu/answering-ttips-critics-regulatory-cooperation-risk-assessment-and-risk-management [https://perma.cc/FGB9-GTWB] [hereinafter Bull, Answering].

[133] *Id.*

cooperation.

2.4. Regulatory 'Collisions'

This section makes the case for more international regulatory cooperation using examples of related to food safety. *Japan-Apples* is an example of a regulatory 'collision'– a historical moment where countries have sought to reduce regulatory differences through a formal trade dispute under the WTO dispute settlement system.

Before discussing other disputes and as an introduction to the WTO framework, nations have long understood that membership in the world trade order signals a willingness to prioritize trade gains and harmonization over sovereignty.[134] The Original GATT agreement of 1947, and the subsequent GATT agreement of 1994, provide countries with autonomy to establish food regulations, within limits. Members have a right to enact domestic regulations[135] (even if enacted at the sub-national level), that are based on science, international standards, and are not more trade restrictive than necessary. Members also have a duty to notify the Sanitary (animal life) and Phytosanitary (plant life) (together, "SPS") Committee[136] of all new regulations that pertain to human and animal plant life and health, and all modifications to existing regulations that do not conform to international standards and produce a significant effect on international trade.[137] Examples include prohibi-

134 Tracey Epps, INTERNATIONAL TRADE AND HEALTH PROTECTION: A CRITICAL ASSESSMENT OF THE WTO'S SPS AGREEMENT (Edward Elgar ed. 2008); see also Susy Frankel, *The Legitimacy and Purpose of Intellectual Property Chapters in FTAs*, in CHALLENGES TO MULTILATERAL TRADE: THE IMPACT OF BILATERAL, PREFERENTIAL AND REGIONAL AGREEMENTS, (Ross Buckley, Vai lo Lo, & Laurence Boulle eds., 2008) 185 – 200.

135 The SPS Agreement uses the terms "measures" and "regulations" somewhat interchangeably. Regardless of the term used, the Agreement is referring to any sanitary or phytosanitary measure such as laws, decrees, or ordinances applied to protection human, animal or plant life or health as defined under paragraph 1 of Annex A to the SPS Agreement.

136 *See* The WTO Agreement on the Application of Sanitary and Phytosanitary Measures, supra 55, at art. 7 (stating that the Committee meets 3 times per year and all 160 WTO members, acceding countries and observers, have the right to attend its meetings).

137 *See* World Trade Organization, Recommended Transparency Procedures (Dec. 1, 2008), https://www.wto.org/english/tratop_e/sps_e/notification_formats_e.htm [https://perma.cc/A9K8-AR6X] (providing recommendations to

tions on the sale of an imported product on health grounds, and positive requirements for imported products (ex. Certification requirements).[138]

Using *Japan-Apples* as an example, a WTO claim begins with a sixty-day consultation period between parties[139] after which, if necessary, a Panel is established to hear the dispute. The Panel delivers a decision, which can be accepted by the opposing party or sent to the Appellate Body on appeal. A claim is grounded on the GATT Agreements—most commonly the SPS Agreement (covering measures which influence domestic food safety and quality, and animal and plant health regulations),[140] and the TBT Agreement (covering measures which affect other technical requirements such as certification, labeling and standardization that apply to agricultural products both domestically and in international trade)[141]. A regulation that restricts international trade may qualify for an exception: GATT Article XX allows governments to enact measures in order to protect human, animal or plant life or health, provided they do not discriminate or use this as disguised protectionism.[142]

ensure regulatory transparency).

138 Sykes, *supra* 49.

139 *See* Dispute Settlement: Understanding on Rules and Procedures Governing the Settlement of Disputes art. 4.7, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter *DSU*] (stating that a complaining party may request for a panel to be established within sixty days upon failure of consultation to settle a dispute).

140 Agreement on the Application of Sanitary and Phytosanitary Measures art. 5.5, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 493 (and by association Article 2.3) [hereinafter *SPS*]. An example of an SPS claim argues that importing countries are not adhering to international standards and that parties experience long delays in completing risk assessments.

141 Agreement on Technical Barriers to Trade art. 1.3, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1886 U.N.T.S. 120 [hereinafter *TBT*]. For a recent WTO TBT case, see Technical Barriers to Trade Standard Committee, Standards Committee Discusses Tyres, Toy Safety and Food, World Trade Organization (Nov. 6, 2015), https://www.wto.org/english/news_e/news15_e/tbt_10nov15_e.htm [https://perma.cc/YHC2-C5KS] ("[When India decided] to limit the entry of apples to the port of Nhava Sheva, some delegations argued that this would increase delays and create additional costs for producers and exporters. India stated that this measure was neither a technical regulation, standard nor conformity assessment procedure, and therefore did not fall within the scope of application of the TBT Agreement.").

142 Article XX of the General Agreement on Tariffs and Trade states: "[s]ubject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on

A total of 502 cases have been brought to the WTO since 1996;[143] roughly one quarter of these[144] (94 cases) implicated food and were brought under the SPS Agreement and the TBT Agreement which can at times involve food products. Forty–three cases (9% of the total) cited the SPS agreement in their requests for consultations[145], and fifty–one cases (10% of the total) cited the TBT in their requests for consultations.[146] Since the start of the WTO, there have been twelve SPS disputes leading to Panels.[147] Refer to the

international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: . . . (b) necessary to protect human, animal or plant life or health[.]" General Agreement on Tariffs and Trade, art XX, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT].

[143] Current Status of Disputes, World Trade Organization, https://www.wto.org/english/tratop_e/dispu_e/dispu_current_status_e.htm [https://perma.cc/8NBZ-XUMK] (last visited 9/12/2016). See also Ambassador Demetrios Marantis, Office of the U.S. Trade Rep. 2013 Report on Sanitary and Phytosanitary Measures, (2013), www.ustr.gov/sites/default/files/2013%20SPS.pdf [https://perma.cc/DVJ6-FSZT] (stating from 2002–12, over 250 SPS disputes were raised under the WTO's dispute settlement system).

[144] *Statistics*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/dispu_e/stats_e.htm [https://perma.cc/G8RB-2J25] (last visited Sept. 12, 2016) (exhibiting that 129 went to a WTO Panel).

[145] *Disputes by Agreement*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A19# [https://perma.cc/K62R-MDTS] (last visited Sept. 12, 2016).

[146] *Disputes by Agreement*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A22# [https://perma.cc/V67S-RG7B] (last visited Sept. 12, 2016).

[147] Alberto Alemano, *The Multilateral Governance Framework for Food Safety: A Critical and Normative Overview*, 9-45, in FOOD SAFETY, MARKET ORGANIZATION, TRADE AND DEVELOPMENT 20 (Abdelhakim Hammoudi et al. eds., Springer Publishers: New York 2015). *See e.g.*, Panel Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WTO Doc. WT/DS26/R/USA (Aug. 18, 1997) [hereinafter EC—Hormones] (detailing a dispute between the U.S. and the EC); Panel Report, *Australia – Measures Affecting Importation of Salmon*, WTO Doc. WT/DS18/R (June, 12 2000) [hereinafter Japan – Salmon] (explaining a dispute between Canada and Australia); Panel Report, *Japan – Measures Affecting Agricultural Products*, WTO Doc. WT/DS76/R (Oct. 7, 1998) [hereinafter Japan – Measures Agricultural Product II] (stating a dispute between the U.S. and Japan); *Japan – Measures Affecting the Importation of Apples*, WTO Doc. WT/DS245/R (June 15, 2003) [hereinafter Japan—Apples] (detailing a dispute between the U.S. and Japan); Summary of Disputes, *Australia – Certain Measures Affecting the Importation of Fresh Fruit and Vegetables*, WTO Doc. WT/DS270/RW (Aug. 29, 2003) [hereinafter Australia – Fresh Fruit and Vegetable] (stating a dispute between Philippines and Australia); Notification of Mutually Agreed Resolution, *Australia – Quarantine Regime for Imports*, WTO Doc. WT/DS287/RW (March 9, 2007) [hereinafter Australia—Quarantine] (terminating a dispute between the EC and Australia); Panel Report: *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WTO Doc. WT/DS291,292, 293/INTERIM (Sept. 29, 2006) [hereinafter EC—Biotech] (stating that the EC violated WTO rules when it imposed a

Appendix for a list.

First, what has emerged from the SPS jurisprudence is a complex set of rulings on questions of sufficient scientific evidence and appropriate risk assessment that constrain the regulatory autonomy of WTO members in the SPS field.[148] The trend is to interpret SPS decisions through a narrow lens that "elevates the policing of trade restrictive measures above the ability of national governments to address risk in the face of scientific uncertainty."[149]

Among the twelve regulatory collisions listed above, *EC-Biotech* is an example of a regulatory collision evolving from philosophical differences. This case involved complaints by the U.S., Canada and Argentina concerning European Community measures (a moratorium on the approval and marketing of biotech products), which allegedly violated the SPS Agreement.

Since the WTO rules state that trade measures must be based on international standards, if international standards exist, they will be used. In the *EC-Biotech* decision, the WTO Panel cited the Codex principles and guidelines on the safety of foods derived from genetically-modified plants, animals and microorganisms.[150]

moratorium on the approval of biotech products); Appellate Body Report, *United States—Continued Suspension of Obligations in the EC—Hormones Dispute*, WTO Doc. WT/DS320/AB/R (Oct. 16, 2008) [hereinafter US – Suspension] (indicating that the U.S. violated WTO rules by failing to remove retaliatory measures against the EC); Summary of Dispute, Australia – *Measures Affecting Importation of Apples from New Zealand*, WTO Doc. WT/DS367 (Sept. 2, 2011) [hereinafter Australia—Apples] (detailing a dispute between New Zealand and Australia); Summary of Dispute, *United States—Certain Country of Origin Labelling Requirements*, WTO Doc. WT/DS384/8 (June 29, 2012) [hereinafter US-COOL (Canada)] (stating a labeling dispute between Canada and the U.S.); Summary of Dispute, *United States Certain Country of Origin Labelling Requirements* (WTO Doc. WT/DS386/7 (Dec. 21, 2015)[hereinafter US-COOL (Mexico)] (stating a labelling dispute between Mexico and the U.S.); Appellate Body Report, *Australia—Measures Affecting the Importation of Apples from New Zealand*, WTO Doc. WT/DS367/AB/R (Nov. 29, 2010) (detailing a dispute between New Zealand and Australia on the importation of apples); Panel Report, *United States—Certain Measures Affecting Imports of Poultry from China*, WTO Doc. WT/DS392/R (Sept. 29, 2010) [hereinafter U.S—Poultry] (stating a dispute between China and the U.S.); Panel Report, *Korea—Measures Affecting the Import of Bovine Meat and Meat Products from Canada*, WTO Doc. WT/DS391/R (July 3, 2012) [hereinafter Korea—Bovine Meat (Canada)] (stating a dispute between Canada and Korea).

148 *See* Mann, *supra* note 35, at 263.

149 *See* Alan O. Sykes, *Domestic Regulation, Sovereignty, and Scientific Evidence Requirements: A Pessimistic View*, 3 CHI. J. OF INT'L L. 368 (2002).

150 *See* Summary of Dispute, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*,WTO Doc. WT/DS 291,292, 293/INTERIM [hereinafter EC – Biotech] (summarizing disputes between the U.S. and EC, between Canada and EC and Argentina and EC).

The United States won *EC-Biotech* but suspended the retaliatory proceedings in the WTO in order to provide the European Union with "an opportunity to demonstrate meaningful progress in the approval of biotech products."[151] This shows that a government that chooses to build a regulatory mechanism addressing the food safety of genetically-modified foods can use Codex text as the baseline, with each government adopting its own GMOs policy.[152] However, given that there are no internationally agreed-upon standards on the *labeling* of genetically modified foods, countries are free to apply their own labeling regulations.

Next, the TBT jurisprudence also demonstrates examples of regulatory collisions regarding labeling, though not necessarily based upon philosophical differences. Generally speaking, TBT jurisprudence[153] has focused on whether a food label amounts to a trade restriction by balancing the discriminatory impacts a label

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[151] Press Release, U.S. Trade Representative, Statement on the EC—Biotech Dispute (Jan. 2008), https://ustr.gov/about-us/policy-offices/press-office/press-releases/archives/2008/january/statement-ec-biotech-dispute [https://perma.cc/7QF3-33DV].

[152] *FAQs—Question about Specific Codex Work*, CODEX ALIMENTARIUS, http://www.codexalimentarius.org/faqs/specific-codex-work/en/ (last visited Sept. 11, 2016) [https://perma.cc/XE44-AJAA] [hereinafter *FAQ*, Codex] ("Codex has adopted principles and guidelines to assess food safety of foods derived from recombinant-DNA plants, animals and microorganisms.").

A government that chooses to build a regulatory mechanism addressing the food safety of GM foods can use Codex text as a basis, but each government is free to adopt its own policy as to the use of GM organisms in the agriculture and other sectors. At the moment, there are no internationally agreed-upon recommendations on the food labeling of GM foods. Governments are therefore applying their own regulations.

[153] *See e.g.*, EC—Biotech, *supra* note 150 (holding that the regulations at bar are not impermissibly restrictive of trade or discriminatory because they are based on legitimate concerns). Panel Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WTO Doc. WT/DS406/R (Sept. 2 2011) [hereinafter US—Clove Cigarettes] (analyzing whether the U.S. ban on clove cigarettes was inconsistent, discriminatory, and necessary to achieve the end of reducing youth smoking.); US-COOL (Canada), *supra* note 147 (analyzing whether the country of origin labeling requirements under U.S. law give less favourable treatment to foreign goods, namely imported livestock products); Panel Report, *United States—Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, WTO Doc. WT/DS381/R (Sept. 15, 2011) [hereinafter US—Tuna] (analyzing whether the "dolphin-safe labeling standards" discriminated against Mexican tuna products, and whether the regulations were necessary); Appellate Body Report, *United States—Measures Concerning the Importation Marketing and Sale of Tuna and Tuna Products*, WT/DS381/AB/R (May 16, 2012) [hereinafter US—Tuna II Appeal] (analyzing whether the "dolphin-safe labeling standards" discriminated against Mexican tuna products, and whether the regulations were necessary).

may have on imports against the legitimate purpose of the label itself. Several WTO cases that implicate the TBT Agreement have involved whether the state has managed the use of the label; whether the label conforms to international standards; and whether the application of the labeling standard discriminates between imports and like domestic products.[154]

Perhaps you have seen a package with the label, "*dolphin safe*." This label was the focus of a recent WTO challenge wherein the TBT Agreement was successfully invoked to overturn a federal U.S. food labeling standard on tuna. This case, *U.S-Tuna,* involved a regulatory collision – between the U.S. and its desire to regulate fishing practices (the use of fishing nets that are dangerous to dolphins) through a mandatory food labeling standard ("dolphin safe"), and Mexico's fishing practices.[155] Mexico challenged these rules under the TBT agreement,[156] making three leading claims: that United States dolphin-safe labelling provisions discriminate against Mexican tuna products, that the United States dolphin-safe labelling provisions are more trade-restrictive than necessary to fulfill the legitimate objectives, and lastly, that United States dolphin-safe labelling provisions violate the requirement that regulations be based on relevant international standards where possible.[157] In the end, a WTO panel struck down the labeling statute. In another high-profile case, the United States lost a WTO challenge and was asked to weaken domestic regulations to comply with a ruling on the Country of Origin Labeling Rule.[158]

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[154] Elizabeth Trujillo, Draft, *New Visions for International Trade and Sustainable Development* (Nov. 2015).

[155] US – Tuna, *supra* note 153; US-Tuna II Appeal, *supra* note 153.

[156] *See* Agreement on Technical Barriers to Trade, art. 2.1, 2.2, 2.4, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 1868 U.N.T.S. 120 (establishing standards for regulation in order reduce barriers to trade).

[157] US—Tuna, *supra* note 153.

[158] The COOL rule requires retail food stores to inform consumers about the country of origin of fresh fruits and vegetables, fish, shellfish, peanuts, pecans, macadamia nuts, ginseng, and ground and muscle cuts of beef, pork, lamb, chicken, and goat. The rule has been controversial with respect to meat products, leading Canada and Mexico to challenge the rule in the WTO, arguing that COOL has a trade-distorting impact by reducing the value and number of cattle and hogs shipped to the U.S. market. In 2011, a WTO Panel found COOL rules to be in violation of the WTO, in 2012 the U.S. appealed, and was asked to amend the rule. After doing so, it is waiting for a decision from the WTO compliance panel to determine if the final COOL rule complies with WTO findings. *See also*, Dan Flynn, *New COOL Rule Might Result in Retaliatory Tariffs,* FOOD SAFETY NEWS (May 24, 2013), available at http://www.foodsafetynews.com/2013/05/new-cool-rule-

A WTO claim can have many implications and has the potential to shape domestic and transnational regulatory governance through broader systemic influences.[159] The SPS and TBT agreements have been found to offer the same level of right to regulate, with the TBT jurisprudence showing a more cautious stance.[160] While much of the litigation under SPS and TBT Agreements has led to a clarification of a regulatory norm, the cases where the dispute took a long time to resolve or continues to persist (*see, e.g.*, *U.S.-Tuna*) are more troublesome and underscore a need for cooperative regulation.[161]

Critically, countries have gone so far as continuing to violate the WTO rules to preserve their right to regulate (*see e.g.*, *EU-Hormones*, the SPS case involving a European Union ban on meat imports treated with hormones).[162] *EU-Hormones* illustrates that, for WTO members, the rules constrain the right to regulate only by making it more costly to exercise that right. The European Union lost this case based on their adherence to the precautionary principle, and incurred trade-related remedies to the United States. This illustrates that while most WTO Members view the rules as 'hard' constraints, some treat them as 'soft' constraints.

might-result-in-retaliatory-tariffs/#.U-gQrGPou8w [https://perma.cc/T9RG-NZ3K) (discussing potential retaliatory tariffs that Mexico and Canada could put in place after U.S. issued its regulation); Tenille Tracey, *House Votes to Remove Country of Origin Labels on Meat Sold in the U.S.*, WALL STREET JOURNAL, June 10, 2015, available at http://www.wsj.com/articles/house-votes-to-remove-country-of-origin-labels-on-meat-sold-in-u-s-1433990294 [https://perma.cc/9X4B-LAUC] ("The House voted late Wednesday to remove country-of-origin labels on beef, pork and chicken sold in the U.S., hoping to prevent a protracted battle over the labels with Canada and Mexico").

159 *See generally* Gregory C. Shaffer, *How the WTO Shapes Regulatory Governance,* 9 REG. & GOVERNANCE, 1 (2015) (providing a framework for assessing the regulatory implications of the WTO).

160 *See* Wagner, *Regulatory Space*, *supra* note 2 at 66-67 (seeking to balance liberalization of trade obstacles and state regulatory rights).

161 *See e.g.,* US—Tuna, *supra* note 153; US—Tuna II Appeal *supra* note 153 (noting that in the US – Tuna II Art. 21.5 Appeal, the Appellate Body did not clarify how the US should change its dolphin-safe tuna labeling scheme for it to become compliant with WTO law. The judges stressed that, however, the measure lacked even-handedness in application, as it left US consumers with the risk of buying dolphin-unfriendly tuna products.)

162 Compare how the EC continued to violate the WTO rules inEC— Hormones with U.S. behavior-the U.S. rescinded Country of Origin Labeling ("COOL") after the recent WTO ruling in US-COOL.

2.5. 'Imminent' Regulatory Collisions

Not all regulatory differences result in outright collisions, and many WTO trade disputes are resolved or prevented before they reach the consultation phase. This section describes 'imminent collisions'—or regulatory differences, which may collide in the WTO, that show the most promise for cooperation.

The data on 'imminent collisions' come from: formal notifications made by WTO Members to the WTO SPS or TBT Committees concerning newly adopted SPS or TBT measures, and informal concerns stemming from controversial regulations in the United States and elsewhere.

The first source of data on imminent collisions comes from formal notifications from WTO Members to the WTO SPS Committee of any newly adopted SPS measures, or SPS measures which have been changed. Under the WTO SPS and TBT Committees, members are free to raise Specific Trade Concerns (STCs) about other members' measures, which they believe are inconsistent with provisions of the SPS or TBT Agreements.[163] An examination of current concerns before these two reveals the type of regulatory collisions that are quelled before reaching the consultation phase. Since 1995, when the SPS Agreement was established, 312 STCs regarding SPS measures were raised, 28% of these concerning food safety. Twenty-two food-standard-related STCs were raised in 2010-11, nine regarding chemical maximum residue limits, six regarding specific foods, and two regarding labeling. These cases illustrate that SPS measures are actively contested.

A recent meeting of the Committee on Technical Barriers to Trade examined 92 STCs regarding TBT measures in 2015 – the second-highest number in a single year since 1995.[164] In the TBT arena, STCs can relate to standards, testing and certification procedures, regulations or labeling requirements imposed by the importing country, and are said to impact companies producing these goods and consumers who use them. Two of the three most criti-

[163] *See* e.g. Note by the Secretariat, *Specific Trade Concerns*, WTO Doc. G/SPS/GEN/204/Rev.16 (Feb. 23, 2016) (exemplifying an instance of member states raising trade concerns).

[164] WORLD TRADE ORGANIZATION, Minutes of the meeting of Nov. 4-6, 2015, https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=231304,230729,228723,226671,134466,132661,132294,130728,130294,127112&CurrentCatalogueIdIndex=3&FullTextHash= .

cal TBT concerns relate to food. The first STC related to a proposed European Union ban on products derived from cloned animals,[165] where the United States and Brazil considered that this proposed measure may be more trade restrictive than necessary, and questioned the supporting scientific evidence. The EU provided an update on the ongoing decision-making process for this measure and expressed its willingness to further discuss the matter. The second STC related to the limitation of entry points for *apples* into India and a European Union decision to withdraw "equivalence" recognition of Indian *organic products*.[166]

One final observation is that many STCs relate to labeling. Labeling concerns are increasingly important in the TBT Committee – a timely and relevant topic for the United States where nearly 300 food labeling bills were introduced in state legislatures in 2014-15, including: nutrition disclosures, sugary drinks warnings, identification of local products such as olive oil and seafood, and disclosure of GMO ingredients. Indonesia, the EU, India, Ecuador and Chinese Taipei have brought STCs regarding labeling regulations on: sugar, salt and fat content, health messages on processed and packaged foods, different types of oils, genetically modified foods, and the inclusion on labeling of foods which are endocrine disruptors.[167]

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[165] *Id*. Specifically, the STC was from the European Union — Proposal for a Directive of the European Parliament and of the Council on the Cloning of Animals of the bovine, porcine, ovine, caprine and equine specifies kept and reproduced for farming purposes (197) and Proposal for a Council Directive on the placing on the market of food from animal clones (198).

[166] "With respect to India's decision to limit the entry of apples to the port of Nhava Sheva, some delegations argued that this would increase delays and create additional costs for producers and exporters. India stated that this measure was neither a technical regulation, standard nor conformity assessment procedure, and therefore did not fall within the scope of application of the TBT Agreement. Regarding the EU decision to no longer recognize equivalence of India's organic products, India was of the view that this measure was overly burdensome for producers and would hinder trade with the EU. The EU in turn argued that India had not satisfied provisions contained in the bilateral agreement which recognized such equivalence." WTO, *Standards Committee Discusses Tyres, Toy Safety and Food*, https://www.wto.org/english/news_e/news15_e/tbt_10nov15_e.htm (last accessed Sept. 21, 2016) [https://perma.cc/SX2J-HALF].

[167] The regulations are: inclusion of sugar, salt and fat content information, as well as health messages on the label of processed foods (Indonesia); Categorization of Compounds as Endocrine Disruptors' (EU); Processed and Packaged Food Products (Ecuador); Canola Oil (India); genetically modified foods (Chinese Taipei). *See Technical Barriers to Trade*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm (last viewed on 9/30/2016) [https://perma.cc/9B6R-STYG] (providing a data base for viewing

Labeling rules corresponding to GMOs are an imminent regulatory collision. Recall the discussion of *AquAdvantage*, an FDA-approved genetically modified salmon produced in the United States. As noted previously, the United States and European approaches to regulating the production, cultivation, and trade in GMOs differ. The labeling of GMOs is a controversial issue in the United States, with recently passed Federal GM legislation preempting individual state laws on the matter.[168] The topic is equally controversial outside the United States where rules on genetically modified foods differ widely.

Generally speaking, in the United States and elsewhere, many food regulations are being proposed that could evolve into imminent collisions. While, as noted, future measures to protect public health, animal health and plant health may include labeling of GMOs, future measures may also include: a ban on products related to cloning, the use of growth hormones and endocrine disrupting chemicals, antimicrobial resistance to antibiotics, plant synthetic biology, and laws related to the humane treatment of animals – such as the 'State of California's Egg Rule' regulating the humane treatment of egg-laying chickens.[169]

The regulation of nanotechnology is likely to invoke a regulatory collision. Nanotech is a new frontier[170] backed by a billion-dollar industry, which is expected to grow.[171] Every major food corporation either has a program in nanotech or is looking to de-

regulations and cases).

[168] Mary Clarke Jalonick, *Obama Signs Bill Requiring Labeling of GMO Foods,* WASHINGTON POST (July 29, 2016), https://www.washingtonpost.com/lifestyle/food/obama-signs-bill-requiring-labeling-of-gmo-foods/2016/07/29/1f071d66-55d2-11e6-b652-315ae5d4d4dd_story.html [https://perma.cc/P8RQ-WSRS]. For the individual state legislation this preempted, see *State Labeling Initiatives*, CENTER FOR FOOD SAFETY (2015), http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/state-labeling-initiatives# [https://perma.cc/K5XR-KT6C].

[169] *See e.g.* Treatment of Farm Animals Prohibitions, Cal. Health & Safety Code § 25990 (West) (requiring poultry eggs to come from chickens that have enough room to fully extend their limbs and turn around freely); Labeling of Food Produced with Genetic Engineering, Vt. Admin. Code 3-2-118A:CP 121 (requiring labeling of genetically modified foods); *see also* Regulation (EU) 2015/2283, 2015 O.J. (L 327) 1 (the European Union's regulation on nanofoods and cloned foods).

[170] *See generally FAO/WHO Expert Meeting*, *supra* note 6.

[171] *See* Tiju Johnson and Mark Morrison, *Nanotechnology in Agriculture and Food*, EUROPEAN NANOTECHNOLOGY GATEWAY (Apr. 2006) ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nanotechnology_in_agriculture_and_food.pdf [(citing a report produced by Helmut Kaiser Consultancy, entitled *Nanotechnology in Food and Food Processing Industry Worldwide*).

velop one.[172] And while such nanotechnology ingredients can be beneficial (holding promise in their ability to combat issues such as obesity, malnutrition), scientists are considering their potential health and safety risks for consumption.[173] The FDA does not require nanoparticles to be labeled in foods but some consumers in the United States are lobbying for it. Meanwhile, Codex sets standards on food additives, but does not set standards on either the use of nanotechnology in food or GMO labeling,[174] making these issues ripe for an 'imminent' regulatory collision.

The STCs illustrate that the field of possible disputes is larger than actual disputes which reach the WTO. These imminent collisions could be resolved through more mechanisms for international regulatory cooperation.

3. THE PROBLEM: CURRENT TREATIES DO NOT MEET THE DEMAND FOR MORE COOPERATIVE REGULATION

New approaches to IRC are needed to raise levels of food safety, to keep pace with emerging new technologies in food production and to mollify intensifying philosophical differences, regulatory collisions, and imminent regulatory collisions. This section describes a wish list for cooperative regulation to increase food safety-essentially, what is missing from traditional approaches to international regulatory cooperation leading to a new framework for cooperative regulation -- found in the Mega-Regional.

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172 *See* Gaidos, *supra* note 7 (quoting Jozef Kokini, the Director of the Center for Advanced Food Technology at Rutgers University, USA).

173 *Id*.

174 *See FAQ,* Codex *supra* note 152 ("Codex has adopted principles and guidelines to assess food safety of foods derived from recombinant-DNA plants, animals and microorganisms. If a government chooses to build a regulatory mechanism to address the food safety of so-called GM foods, then they can use Codex text as a basis for it. This being said, each government is free to adopt its own policy as to the use of GM organisms in the agriculture and other sectors. At the moment, there are no internationally-agreed recommendations on the food labelling of GM foods. Governments are therefore applying their own regulations.").

3.1. *The 'Wish List' for Expanding Cooperative Regulation to Raise Food Safety*

While countries face a menu of challenges, they also have a list of IRC techniques at their disposal. To strengthen food safety, for example, the United States uses some but not all techniques. This section provides a 'wish list' for cooperative regulation and proposes the TPP as a mechanism for improving IRC and food safety.

The WHO and the FAO have identified specific IRC needs with respect to food safety risks. The World Health Organization reports that surveillance of foodborne diseases is becoming an increasingly high priority on the public health agenda of many countries.[175] Cooperation is required on many levels—in the rapid detection of incidents, identification of causative agents and foods, and the prompt and effective response to contain and mitigate any adverse health and economic effects. This includes maintaining sensitive and rapid alert systems, detailed and well-tested preparedness plans, and rapid and effective emergency response systems with links to relevant international networks.[176]

Meanwhile, the FAO notes that many non-industrialized countries lack the resources to conduct meaningful surveillance, and even the countries that undertake surveillance may be using different methods and have different standards.[177] These countries need trained staff in government, adequately staffed and equipped laboratories, and trained health care professionals to identify and report diseases and timely alerts via current notification processes.[178] Establishing consistent laboratory methodologies and training, emergency preparedness training and procedures, database development, further assistance for non-industrialized countries, and strengthened communication networks are key strategies to advance the status of international foodborne disease surveillance. Finally, the FAO notes that even in the United States, agencies face problems with coordination in that the USDA and the FDA would benefit from better coordination, both nationally and internationally, linking surveillance outcomes with what we observe with foods

[175] *Id.*

[176] *See* FAO, *International Cooperation*, *supra* note 65 (discussing the international coordination of response systems to food safety risks).

[177] *Id.*

[178] *Id.*

in the United States.[179]

Other elements on the 'wish list' are mechanisms to assist with risk assessment (the objective evaluation of the risk of certain activities) or risk management (the subjective process by which regulators use the data produced during risk assessment and, combining data with relevant policy considerations, determine society's risk preferences and what regulations are required to achieve those preferences).[180] This emerges from the rise in trade conflicts related to philosophical differences and points to a need to coordinate regulatory policy in a way that manages and reduces those differences. In the case of genetically modified foods, the regulatory problem is clear: while one side (the European Union) strongly supports regulations designed to prohibit or label genetically modified foods (risk management), the other side (the United States) counters that existing scientific studies identify little to no risk with such products (risk assessment).[181] Here, regulatory disparities are not accidental:[182] both sets of regulators are relying on disparate scientific studies, not because their citizens exhibit a unique level of risk tolerance. While it may be impossible to separate issues of risk assessment and risk management[183], regulatory cooperation on risk assessment may be possible through dialogue, information sharing, and scientific fact-finding.[184] Cooperation on risk assessment is possible by examining the science behind various regulatory approaches and determining which approach aligns with prevailing

[179] *Id.*

[180] *See* Bull, *Developing a Domestic Framework for International Regulatory Cooperation*, *supra* note 34 (detailing a vision of cooperation in international regulatory risk assessment and risk management). *See also* Bull, *Answering*, *supra* note 132 (suggesting more careful disambiguation of risk assessment and risk management within the Transatlantic Trade and Investment Partnership).

[181] *See* Bull, *Answering*, *supra* note 132 (discussing risk assessment with genetically modified foods and other "unnatural" agricultural products).

[182] *See* Bull, *Developing a Domestic Framework for International Regulatory Cooperation*, *supra* note 34 at 58 (noting that accidental disparities have occurred when "trading partners have historically failed to coordinate regulatory policy and therefore often enact divergent regulatory approaches merely as a matter of historical accident").

[183] Risk management is subjective and depends on the risk tolerance of the population at issue. For instance, the level of confidence required to accept a finding as "proven" (e.g., a 95% level of confidence, or a 99% confidence interval), while essential to scientific investigations, represents a risk management determination.

[184] *See* Bull, *Answering*, *supra* note 132 (suggesting a more careful disambiguation of risk assessment and risk management within the Transatlantic Trade and Investment Partnership).

scientific knowledge.[185] All credible scientists subscribe to the scientific method as the mechanism applied to testing existing views, theories, and uncovering facts.[186] At some point, scientists will decide on a result using available data and empirical methods to test hypotheses. And at some point, agencies will decide to foreclose consideration of any additional evidence in order to make a regulatory decision.[187] Information-sharing among scientists worldwide can mitigate this problem by ensuring that new studies will diffuse as rapidly as possible across international boundaries. As Reeve Bull points out, "the Administrative Conference of the United States has recommended that regulatory scientists work with their international counterparts to share data sets, divide responsibility for conducting otherwise duplicative tests, and achieve the efficiencies that arise from maintaining a global network of researchers."[188]

Cooperation on risk management is more challenging because it depends on the public's level of risk tolerance[189], even if the general public is more impressionistic than scientific[190] and even when decision-making is skewed or captured.[191] One suggestion is to enhance citizen input in agency policymaking, leading citizens to

185 *See* Bull, *Developing a Domestic Framework for International Regulatory Cooperation*, *supra* note 34 at 63 (suggesting methods to increase regulatory cooperation in risk management).

186 *See* John L. Campbell, INTRODUCTION TO SCIENCE AND THE SCIENTIFIC METHOD (2008) at 11 (cataloguing the scientific method's rise to general acceptance in the community of scientists).

187 *See* Wendy E. Wagner, SCIENCE IN REGULATION: A STUDY OF AGENCY DECISIONMAKING APPROACHES 26–27 (2013), https://web.archive.org/web/20160514055832/http://www.acus.gov/sites/default/files/documents/Science%20in%20Regulation_Final%20Report_2_18_13_0.pdf [https://perma.cc/CWK5-3NSL] (describing these rules as "Stopping rules").

188 *See* Bull, *Developing a Domestic Framework for International Regulatory Cooperation*, *supra* note 34, at 61 (citing the Administrative Conference of the United States, Recommendation 2011-6, International regulatory Cooperation, ¶¶ 3 – 6, 77 Fed. Reg. 2257, 2260-61 (Jan. 17, 2012), and providing examples of facilitating information sharing).

189 *Id.* at 63.

190 *See* Richard H. Pildes and Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 55 – 56 (1995) (noting that "lay people assess risk through different value frameworks rather than those implicitly embedded in expert approaches").

191 *See* Wendy E. Wagner, *Administrative Law, Filter Failure, and Information Capture,* 59 DUKE L. J. 1321, 1324 – 25 (2010) ("In the regulatory context, information capture refers to the excessive use of information and related information costs as a means of gaining control over regulatory decisionmaking in informal rulemakings").

change policy from the "bottom up".[192] Of course, cooperation is possible if there are areas of mutual regulation. For instance, in some contexts, the United States and European Union regulations exhibit similar levels of precaution (e.g., auto safety standards), and the likelihood of reaching agreement or mutual recognition is considerably greater in those areas.[193]

3.2. Comparing Traditional Agreements with the 'Wish List'

International economic treaties (Bilateral Investment Treaties[194] and WTO Agreements, for example) have traditionally helped regulators from different countries working together to increase understanding of regulations across boundaries and influence rule making from the bottom up.[195] While Bilateral Investment Treaties promote standard-setting, harmonization and equivalence[196], often

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[192] *See generally* Reeve T. Bull, *Making the Administrative State "Safe for Democracy": A Theoretical and Practical Analysis of Citizen Participation in Agency Decisionmaking*, 65 ADMIN. L. REV. 611 (2013) (arguing that agencies should seek enhanced public input when it actually promotes a better outcome).

[193] *See* Bull, *Answering*, *supra* note 132 (discussing regulatory convergence when both sides treat issues with comparable levels of precaution).

[194] Traditional investment agreements like the Model U.S. Bilateral Investment Treaty are similar to Investment Chapters found in regional trade agreements with an investment chapter (e.g., The North American Free Trade Agreement, Chapter 11) and typically protect covered investments with "minimum standards" and "fair and equitable treatment."

[195] *See* Ann-Marie Slaughter, *Governing the Global Economy through Government Networks, in* THE ROLE OF LAW IN INTERNATIONAL POLITICS: ESSAYS IN INTERNATIONAL RELATIONS AND INTERNATIONAL LAW 204 (Michael Byers ed., 2000) (discussing the role of international government networks). *See* also Janet Koven Levit, *A Bottom-up Approach to International Lawmaking: The Tale of Three Trade Financial Instruments*, 30 YALE J. INT'L L. 125 (2005) (analyzing the bottom-up approach in three instruments—letter of credit, export credit insurance, and the official export credit guarantee); Kal Raustiala, *The Architecture of International Cooperation: Transgovernmental Networks and the Future of International Law*, 43 VA. J. INT'L L. 1 (2002) (arguing that the development of linkages among government officials from diverse jurisdictions-peer-to-peer, using informal, often non-binding agreements, and with limited oversight by foreign ministers-has been increasingly recognized as an important component of contemporary cooperation).

[196] *See European Commission Releases Draft Proposal on TTIP Investment Court*, BRIDGES (Sept. 17, 2015), *available at* http://www.ictsd.org/bridges-news/bridges/news/european-commission-releases-draft-proposal-on-ttip-investment-court [https://perma.cc/EKN3-X2BM] (noting that protections include "guarantees against expropriation without compensation; the possibility of transferring investment-related funds, commitments to ensure fair and equitable treatment and physical security, commitments that governments respect obligations to investors that are written and legally binding, and guarantees of compen-

in food related investment[197], the focus here is on the WTO Agreements and trade-related measures because those Agreements directly affect food safety and because those Agreements bind all 160 member nations.

Members of the WTO ascribe to a baseline level of cooperative regulation. The original GATT agreement of 1947 originated in the postwar era—a period when policymakers fought to build a multilateral open world economy that was compatible with the desire for national policy autonomy.[198] Revised in 1996 when the WTO was formed, the GATT obligates Members to harmonize trade relations by reducing tariffs, removing non-tariff barriers, and promoting free trade. Provisions such as most-favored-nation (GATT Article III) and national treatment (GATT Article IV) give members the right to enact regulations on food and plant life that do not discriminate against other nations or similar products. And, as noted earlier, two WTO Agreements—the SPS Agreement and the TBT Agreement—promote harmonization and standard setting.

The SPS Agreement encourages regulatory cooperation through standard-setting, harmonization, and equivalence. In terms of harmonization, according to the WTO SPS Agreement, Members have the right to regulate "to enact necessary measures" (SPS Article 2.1) "to the extent necessary to protect human, animal or plant life or health" (SPS Article 2.2) so long as trade measures are not disguised trade restrictions.[199] The SPS Agreement encourages governments to apply measures that are based on international standards (SPS Article 3.1)[200]—which, for international food standards (such as packing and labeling) are the standards approved by Codex. Similarly, WTO Members are encouraged to base their domestic veterinary legislation on the international reference standards adopted by the World Organization for Animal Health.[201] Standards beyond international standards are allowed

sation for those losses that arise in specific circumstances, such as armed conflicts").

[197] Investment chapters have the ability to stimulate investment in food and agriculture—such as investments can be in farmland, food processing, agricultural inputs and services, wholesale distribution, and retail networks.

[198] John G. Ruggie, *International Regimes, Transactions, and Change: Embedded Liberalism in the Postwar Economic Order*, 36.2 International Organization 379, 379 – 415 (1982).

[199] SPS Agreement, *supra* note 55.

[200] *See id*. at art. 3.1, 3.2, and Annex A(3) (outlining specific provisions on harmonization).

[201] In the absence of domestic legislation, contractors could request that pro-

but only "if there is scientific justification" (SPS Article 3.3).[202] Finally, the SPS encourages equivalence for a specific measure or measures related to a certain product or categories of products, or on a systems-wide basis (SPS Article 4).[203] It emphasizes that equivalence of SPS measures does not require duplication or sameness of measures, but the acceptance of alternative measures that meet an importing Member's appropriate level of SPS protection.[204]

Next, the WTO TBT Agreement preamble directly speaks to standard-setting by stating that it seeks "to encourage the development of such international standards and conformity assessment systems" and to ensure "that technical regulations and standards, including packaging, marking and labelling requirements, and procedures for assessment of conformity with technical regulations and standards do not create unnecessary obstacles to international trade."[205] At the same time, the TBT Agreement recognizes WTO members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health, safety, or the environment. The TBT Agreement, like the SPS Agreement, encourages governments to harmonize technical standards with international standards,[206] unless those international standards are ineffective for fulfilling the legitimate objective of the technical

ducers incorporate farming practices recommended by the OIE (like animal welfare standards), to facilitate access to international markets Several standards apply: for animal health, see the standards and guidelines developed under the auspices of the International Office of Epizootics, and for pant health, see the international standards, guidelines and recommendations under the auspices of the Secretariat of the International Plant Protection Convention (IPPC) in cooperation with regional organizations operating with the Framework of the IPPC.

[202] *See* SPS Agreement, *supra* note 55 at art. 3.3 ("Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification").

[203] *See id.* at art. 4 (encouraging equivalent treatment between sanitary or phytosanitary measure of other members to the agreement).

[204] *Id.*

[205] Agreement on Technical Barriers To Trade, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex A 1868 U.N.T.S. 120 (1994) [hereinafter TBT Agreement]

[206] However, the TBT does not define 'international standard'. *See* WTO Newsroom on the TBT, World Trade Organization (2016), https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm [https://perma.cc/Z3VM-S6JT] (summarizing news on the TBT agreement).

regulation.[207] Like the SPS, it also encourages 'standard equivalence' between countries—the formal acceptance of the standards of other countries through explicit agreements.[208] And like the SPS, it mandates that countries establish inquiry points and national notification authorities in order to answer questions about TBT regulations and to notify other WTO members of new regulations.[209] Finally, the TBT Agreement also encourages WTO Members to enter into negotiations with other Members for the mutual acceptance of conformity assessment results.[210]

While current treaties promote central IRC principles such as standard-setting, harmonization and equivalence, they are not able to provide everything on the wish list for cooperative regulation. Gaps remain in surveillance of foodborne diseases and coordination (which, for non-industrialized countries, means developing consistent laboratory methodologies and training, emergency preparedness training and procedures, and database development), and in harmonizing risk assessment or risk management.

Current international trade treaties are also unable to resolve some longstanding disputes and lingering issues remain in place. Take for example *US-Poultry,* a WTO case brought by China against the United States for a 2010 ban on Chinese poultry.[211] In this case, the WTO Panel ruled against the United States, stating that the U.S. ban was not supported by scientific evidence. At the time the measures were drafted, regulators were keenly aware of notable food safety breaches in China—the highly publicized melamine in milk and adulterated pet food outbreaks—suggesting that regulators recognized that new supply chain partners (China) may not be able to provide the requisite regulatory framework and suf-

[207] *See* TBT Agreement, *supra* note 205 at art. 2.4.

[208] *See id.* at 2.7 ("Members shall give positive consideration to accepting as equivalent technical regulations of other Members").

[209] *See id.* at art. 2.9 and 5.6 (outlining the notification measures to other nations on new regulations).

[210] *See id*. at art 6.3 ("Members are encouraged, at the request of other Members, to be willing to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment procedures").

[211] *See* Panel Report, *United States-Certain Measures Affecting Imports of Poultry from China*, ¶7.154, WT/DS392/R (Sept. 29, 2010) [hereinafter US-Poultry], *available at* https://www.wto.org/english/tratop_e/dispu_e/392r_e.pdf [https://perma.cc/V5ST-TP6E] (last accessed Sept. 22, 2016) (noting that without a U.S. equivalence determination, China correctly argued, Chinese poultry products could not enter U.S. markets).

ficiently robust public health measures to ensure food safety.[212] Since the *US-Poultry* decision, China banned poultry from the United States for Avian Flu, and the United States is urging China to continue its poultry exports, showing that trade in poultry continues to be problematic between the two countries .[213]

Finally, current international trade treaties have difficulty resolving cases regarding GMOs and food additives, where normative philosophies have a potential to collide.[214] These cases highlight the need for other alternatives, such as regulatory cooperation. The following section shows how Mega-Regionals have the potential to provide more IRC mechanisms with respect to food safety.

4. SOLUTION: THE MEGA-REGIONAL AS A FRAMEWORK FOR ENHANCED COOPERATIVE REGULATION

The process of harmonization that began over forty years ago with the GATT of 1947, and continued twenty years later with the formation of the WTO, is gaining strength with greater determination through a new type of trade agreement, the Mega-Regional.

4.1. Mega-Regionals Expand Cooperation Found in Traditional Treaties

The movement from traditional to modern agreements has

[212] *See* Donald H. Regan, *United States-Certain Measures Affecting Imports of Poultry from China: The Fascinating Case That Wasn't*, 11 WORLD TRADE REVIEW 2, 273, 276 – 7 (2012) (observing that this was the first instance in which the basis for the challenge was the claimed inability of the complainant country to enforce its own food-safety rules). *See also* Lukasz Gruszczynski, *United States-Certain Measures Affecting Imports of Poultry from China – Just Another SPS Case?* 2 EUROPEAN J. OF RISK REGULATION 3, 432, (2011) (outlining the developments in SPS law created by the US-Poultry decision).

[213] *See* William Maudlin, *U.S. Challenges China Over Chicken as Trade Friction Rises: Obama Administration Demands that China Open its Market to U.S. Chicken,* WALL ST. J., May 10, 2016, *available at* http://www.wsj.com/articles/u-s-challenges-china-over-chicken-as-trade-friction-rises-1462881223 [https://perma.cc/V427-S7VB] (detailing the United States challenge to China's trade measure).

[214] *See supra* note 96 at 262 (discussing the challenges that the GMOs cases have put on the dispute settlement system).

been a learning experience; regulators have carried forward successes and make improvements in terms of standard-setting, harmonization, and equivalence. Generally the transnational governance literature shows that regulatory norms do not emerge in isolation, but grow from public and private networks working together to create standards and regulations that are either mandates or that get adopted informally through industry practice, industry consensus, and/or market forces, moving across borders and regimes.[215]

In many ways, the TPP carries forward 'best practices' from prior agreements. First, the TPP carries forward best practices found in domestic policies. For instance, the TPP creates another means for regulators to advance their agencies' regulatory missions. Provisions found in the United States Food Safety and Modernization Act of 2012 are similar to the TPP rules, showing that the TPP reinforces those rules.[216] Second, the TPP also carries forward best practices found in international agreements. While previous international agreements had some safeguards in place[217],

[215] Greg Shaffer, *Transnational Legal Process and State Change: Opportunities and Constraints*, LAW AND SOCIETY INQUIRY, 3 (2012). *See generally,* Shaffer, TRANSNATIONAL LEGAL ORDERS, *supra* note 37 (compiling literature on transnational governance mechanisms).

[216] *Compare* Trans Pacific Partnership ch. 7, art. 7.10,7.12 4 February 2016, available at [Hereinafter TPP SPS], https://ustr.gov/sites/default/files/TPP-Final-Text-Sanitary-and-Phytosanitary-Measures.pdf [https://perma.cc/2YKS-EDQG] ("If an importing Party requires certification for trade in a good,the Party shall ensure that the certification requirement is applied, in meeting the Party' sanitary or phytosanitary objectives, only to the extent necessary to protect human, animal or plant life or health"), with FDA Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications, 21 C.F.R. § 1.651 (2016) (requiring third-party certification bodies accredited under this the FDA guidelines to perform unannounced facility audits and to notify the FDA upon discovering a condition that could cause or contribute to a serious risk to public health).

[217] *See generally* North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17,1991, 32 I.L.M. 289, 1114 (1993) [hereinafter NAFTA]; Treaty Between the United States of America and the Government of [Country] Concerning the Encouragement and Reciprocal Protection of Investment (Revised 2004), http://www.sice.oas.org/trade/nafta/chap-111.asp [https://perma.cc/8RZC-VZM9] [hereinafter US Model BIT]; United States-Colombia Trade Protection Agreement, U.S.-Colom., May 15, 2015, (2015), http://www.state.gov/documents/organization/117601.pdf [https://perma.cc/XM9Q-8MEY]; Free Trade Agreement Between the United States and the Republic of Korea, U.S.-S. Kor., Mar. 15, 2012 (2012), http://2001-2009.state.gov/e/eeb/tpp/c26397.htm [https://perma.cc/XM9Q-8MEY]; United States- Panama Trade Promotion Agreement, Oct. 31, 2012 (2012), http://2001-2009.state.gov/e/eeb/tpp/c26397.htm [https://perma.cc/XM9Q-8MEY]; United

modern agreements like the TPP have more safeguards for investment, competition, the environment, climate, labor, food scarcity, and animal welfare.[218] The TPP includes a dedicated chapter for financial services trade, perhaps because countries like Chile and Malaysia both deployed cross-border financial regulations responding to prior financial crises.[219]

Other best practices found in international agreements are those found generally in the WTO SPS Agreement, and also in the SPS Chapters in other agreements. For instance, the WTO SPS Agreement contains a notification procedure to resolve disputes before they reach the Panel stage. In one study, Professor Alberto Alemano compares the number of specific trade concerns raised in front of the Committee and the limited number of disputes litigated under the SPS Agreement and concludes that the low number of WTO disputes can be attributed to the WTO SPS Committee notification system.[220] From over 300 concerns raised to the SPS Committee, only fifteen led to established Panels.[221] The TPP has a notification process similar to the deliberative process of the SPS Committee to resolve more disputes.

In terms of higher standards, the TPP, like other modern

States-Peru Free Trade Agreement, Apr. 12, 2006, (2006), http://2001-2009.state.gov/e/eeb/tpp/c26397.htm [https://perma.cc/XM9Q-8MEY]; Dominican Republic-Central America Free Trade America, U.S.-Dom. Rep.-Costa Rica-Guat.-Hond.-Nicar., Jun. 30, 2005, (2005), https://ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta/final-text [https://perma.cc/S575-JU2R]; Canadian Model Agreement for the Promotion and Protection of Investments, (Revised 2004), http://www.italaw.com/documents/Canadian2004-FIPA-model-en.pdf [https://perma.cc/A273-NTEL]; EU-Canada (CETA), India and Singapore-EC Negotiating Mandate on Investment, E.U.-Can.-India-Sing., Sept. 15, 2011 (2011), http://www.bilaterals.org/?eu-negotiating-mandates-on [https://perma.cc/C7S4-VR7N] (including safeguards for the environment and labor).

[218] Many modern agreements contain chapters on competition, and other chapters address the use of child labor, deforestation, and wildlife trafficking in other countries to secure unfair trade advantages, in response to requests to level the playing field among trading nations. *See* TPP Draft, *supra* note 27 at ch. 9, art. 9.16; ch. 20, art. 20.10; ch. 19, art. 19.7 (addressing issues of child labor, deforestation, and wildlife trafficking).

[219] *See* Ricardo French-Davis, Kevin P. Gallagher, Mah-Hui Lim, and Katherine Soverel, *Financial Stability and the Trans-Pacific Partnership: Lessons from Chile and Malaysia,* 6 GLOBAL POLICY 4, 330 – 342 (Nov. 2015) (elaborating on the financial stability measures included in the Trans-Pacific Partnership in relation to prior issues in Chile and Malaysia).

[220] *See* Alemano, *supra* note 33 at 20 (noting that the WTO SPS Article 7 states this requirement).

[221] *Id*.

agreements, provides "WTO-*plus*" features—features that provide more trade protection than the WTO agreements.[222] TPP SPS Chapter 7 contains SPS protection that goes beyond protection found in the WTO Agreements, or "WTO-*plus*" features.[223] The TPP goes further to increase food safety cooperation by encouraging more cooperation,[224] more information sharing,[225] and more dialogue in the form of annexes, ad hoc agreements, and memoranda of understanding.[226]

The TPP SPS Chapter mentions that it "builds upon and reinforces" the WTO SPS Agreement.[227] A study of Regional Trade Agreements performed by the OECD found that nearly 40% of them are 'WTO-*plus*' with the inclusion of additional specific commitments and procedures.[228] Regional and Free Trade agreements often include SPS Chapters which are "WTO-*plus*" in that they bring greater standards than those afforded by the WTO, incorporating deeper SPS commitments in the form of annexes, ad hoc agreements, and memoranda of understanding, with procedures to be followed to implement them and/or within a specified time frame. For example, a study of the United States and European Union agreements with Korea, the United States agreement with Panama, and the EU-CARIFORUM Agreement finds that the SPS Chapters of United States agreements are fairly short, primari-

222 *See* Brunet Marks, *supra* note 31 (arguing that "WTO-plus" features generally and "SPS-plus" and "TBT-plus" features provide more than the traditional SPS and TBT protection).

223 *See id.* (describing that range of standards available- the WTO provides 'baseline' standards, with Bilateral and Regional Trade Agreements providing higher-than-the-baseline, SPS-plus standards, with private standards providing the highest level of food safety).

224 *See* Trans Pacific Partnership, *supra* note 216, at art. 7.15 (encouraging parties to explore further areas of cooperation and information exchange on sanitary and phytosanitary matters).

225 *Id.* at art. 7.16.

226 *See* e.g. Trans Pacific Partnership Related Industries, Sanitary and Phytosanitary Letters of Exchange with Chile, Canada and Vietnam. 4 February 2016, https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text [https://perma.cc/D5MR-8QXX] (exchanging letters of understanding on salmonid eggs, milk equivalence, catfish, and offals).

227 *See* Trans Pacific Partnership, *supra* note 216, at art. 7.2b (noting that the TPP builds on and extends the WTO SPS Chapter).

228 *See* Fulponi, Shearer and Almeida, *Regional Trade Agreements-Treatment of Agriculture*, March 31, 2011, OECD Working Paper, http://www.oecd-ilibrary.org/docserver/download/5kgg53fmnjxv.pdf?expires=1473730597&id=id&accname=guest&checksum=195C94EDE3BF7FD88851E93CBFD5435C [https://perma.cc/KDT3-MVRR].

ly functioning to establish a bilateral committee for consultation and coordination for understanding one another's SPS measures and their implementation and to set out responsibilities to establish the committee and hold its meetings. Both agreements exempt their SPS chapters from regional dispute settlement procedures.

Side agreements on equivalency are part of the WTO-*plus*. For example, a side agreement to the United States Free Trade Agreement (FTA) with Panama included Panama's recognition of United States SPS and related regulatory systems as equivalent to Panama's for meat, poultry, dairy and processed products.[229] A side agreement to the US-Colombia FTA and US-Peru FTA included recognition of United States meat and poultry inspection system as equivalent and to accept USDA export certificates.[230] Sometimes countries want to negotiate bilaterally. A good example is China, who sought to resolve the poultry equivalence issue with the United States long before it sought to bring it to the multilateral WTO.[231] The TPP continues a United States tradition of adding side agreements to Free Trade Agreements. The TPP contains five side agreements that are SPS-related—one between United States and Chile regarding Salmonid Eggs, one between United States and Canada regarding equivalence for milk, and two between the United States and Vietnam on catfish and offals (variety meats), respectively.[232]

While the SPS Chapters that the United States drafts are similar to one another, SPS Chapters that the European Union drafts are different from the United States and also from one another.[233] The European Union has Agreements that establish committees,[234] and

[229] *See Agreement Regarding Certain Sanitary and Phytosanitary Measures and Technical Standards Affecting Trade in Agriculture Products*, in BILATERAL AND REGIONAL TRADE AGREEMENTS: COMMENTARY AND ANALYSIS, Simon Lester, Bryan Mercurio (eds.) (2008) at xxviii.

[230] *See id*. at 30 (explaining annexes and *ad hoc* agreements includes in the SPS commitments).

[231] *See* Gruszczynski, *supra* note 212 (discussing the timeline and challenges behind the US-Poultry SPS case).

[232] *See TPP SPS*, *supra* note 216 (containing letters of exchange between the U.S. and Chile, Canada, and Vietnam on regulation of certain foods).

[233] *See Agreement Regarding Certain Sanitary*, *supra* note 229 at 152.

[234] The EU-Korea agreement establishes an on-going committee and places attention to be determining pest-or disease-free areas by a two year 'confidence-building activity', to be confirmed by the WTO SPS Committee. If a party rejects the determination of the other, the parties may begin consultations with each agreeing to be open for inspection, testing and other procedures.

some that do not.[235] There is a trend to include provisions on mutual recognition in international agreements.[236]

4.2. Mega-Regionals Provide New Mechanisms for Regulatory Cooperation

Mega-Regionals are a relatively new and unexplored phenomenon, judging from an emerging literature of primarily economic working papers and studies predicting gains and losses.[237] But as a new mechanism for cooperative regulation, they show great promise. These agreements are expansive and provide regulatory flexibility (the 'right to regulate')[238] in a number of areas: to regulate in

[235] *See Agreement Regarding Certain Sanitary*, *supra* note 229 at 152. (commenting that the EU-CARIFORUM agreement does not have a committee but focuses more on cooperation for technical assistance for SPS-type measures within the region and to promoting harmonization of standards with the possibility of bilateral equivalency agreements).

[236] The Asia-Pacific Economic Co-operation Mutual Recognition Agreement represents an improved example of a multilateral agreement. The APEC Mutual Recognition Arrangement of Food and Food Products consists of a framework arrangement and separate implementation arrangements. In these Arrangements the importer accepts that food conforms to the other party's requirements. *See* WORLD ECONOMIC FORUM, *supra* note 23 (analyzing the overall impact of mega-regional agreements on among other things, food safety measures).

[237] *See* Brook K. Baker & Katrina Geddes, *Corporate Power Unbound: Investor-State Arbitration of Intellectual Property Monopolies: Eli Lilly v. Canada and the Trans Pacific Partnership*, *in* NE. PUB. L. AND THEORY FACULTY RESEARCH PAPERS SERIES 42-2015 (2015) (addressing Intellectual Property and the TPP); *Mega-Regional Trade Agreements, Game Changers or Costly Distractions for the World Trading System*, WORLD ECONOMIC FORUM (July 2014), http://www3.weforum.org/docs/GAC/2014/WEF_GAC_TradeFDI_MegaRegionalTradeAgreements_Report_2014.pdf [https://perma.cc/KL5B-2GG5] (discussing the utility of Mega-Regional Trade Agreements); Remy Jurenas, *How Could Mega-Regional Trade Negotiations Affect Agriculture and Food Trade* (Int'l Ctr. for Trade and Sustainable Dev., Issue Paper No. 57, 2015), http://www.ictsd.org/sites/default/files/research/How%20Could%20Mega-Regional%20Trade%20Negotiations%20Affect%20Agricultural%20and%20Food%20Trade.pdf [https://perma.cc/7F6B-U6SF] (explaining how Mega-Regional Trade Negotiations affect food trade); David A. Gantz, *The TPP and RCEP: Mega Trade Agreements for the Pacific Rim,* Arizona Legal Studies Discussion Paper No. 15-36 (2015), *published* at 33 Ariz. J. Int'l & Comp. L. 57 (2016) (explaining the impact of Mega-Regional trade agreements on non-parties); *see also* Dan Ciuriak & Harsha Vardhana Singh, *Mega Regional Trade Agreements: How Excluded Countries Can Meet the Challenge* 8 (2015), http://www.ipekpp.com/admin/upload_files/Report_3_54_Mega_6009607286.pdf [https://perma.cc/8VLS-SKC3] (including a review of economic studies calculating gains and losses).

[238] Other mega regionals, however, have the 'right to regulate' language ex-

the public interest,[239] for financial stability, for the environment,"[240,] and for public health.[241] Even more, the TPP requires new, more committed levels of cooperation compared to looser forms of cooperation found in other agreements (such as principles-based international standards, information sharing, research collaboration, international early warning systems, and capacity building).

Most importantly, however, the TPP breaks with prior economic treaty conventions in that it introduces three *new mechanisms* for cooperation.[242] First, the TPP responds directly to the need for a more deliberative process for SPS related issues by adding a new due process element for countries to discuss issues of concern: a 'Cooperative Technical Consultation'.[243] This feature is a mechanism for a quick determination on an SPS dispute between members before resorting to the dispute settlement provisions of the agreement or to the WTO. While the TPP does not specifically

plicitly in the text. The draft TTIP includes language specific to the "right to regulate": Article 2 affirms that the provisions "shall not affect the right of Parties to regulate within their territories through measures necessary to achieve legitimate policy objectives, such as the protection of public health, safety, environment or public morals, social or consumer protection or promotion and protection of cultural diversity." *See European Commission Releases Draft Proposal on TTIP Investment Court*, BRIDGES WEEKLY (Sept. 7, 2015), http://www.ictsd.org/sites/default/files/review/bridgesweekly19-30.pdf [https://perma.cc/7QCJ-W979] (demonstrating that a newly elected official has the 'right to regulate' policy in Australia).

239 *See* Att'y Gen.'s Dep't, Gov't of Austl., *Tobacco Plain Packaging – Investor Arbitration*, https://www.ag.gov.au/tobaccoplainpackaging [https://perma.cc/KX8N-U8HL] (last visited Oct. 5, 2016) (discussing the public health concerns behind the passage of a Tobacco Act in Australia).

240 *See* Hale, *supra* note 15 (commenting on the opening remarks to the TPP Investment Chapter); s*ee also Tradewinds*, The Official Blog of the USTR, (March 2014), https://ustr.gov/about-us/policy-offices/press-office/blog/2014/March/Facts-Investor-State%20Dispute-Settlement-Safeguarding-Public-Interest-Protecting-Investors [https://perma.cc/4SW4-35H9] (explaining how the United States' trade agreements protect Americans doing business in the United States).

241 Public health measures are described in the TPP with reference to adopting tobacco control measures in order to protect public health. Member parties cannot use the Investment Chapter to bring investment claims against one another's tobacco control measures.

242 *See* Simon Lester & Inu Barbee, *The Challenge of Cooperation: Regulatory Trade Barriers in the Transatlantic and Investment Partnership*, 16 J. OF INT'L ECON. L. 847-867 (2013) (noting that some claims of potential benefits of the TTIP are overstated, but facilitating regulatory cooperation is nevertheless very much worth undertaking).

243 *See* TPP SPS, *supra* note 215, at ch. 7, art. 7.17 (outlining the protocols and procedures countries must follow regarding sanitary and phytosanitary measures).

mention nanotechnology, one could foresee importing countries establishing SPS measures (for example, labeling measures) that are not scientifically based on nanofoods and nanotechnology (the European Union already has a moratorium on nanofoods and labeling requirements, so countries also adhering to the precautionary principle could potentially do the same)[244]. If United States exports incorporating nanotechnology are banned, United States regulations on food additives (where Codex sets a standard) and nanotechnology (where Codex does not set a standard) could come under review under the 'Cooperative Technical Consultations' provision.[245]

Second, the TPP contains a 'Regulatory Coherence Chapter', a new feature to trade agreements, as an explicit and strong commitment to regulatory cooperation.[246] Although much of the Regulatory Coherence Chapter needs to be further clarified, chapters like this are not found in traditional (WTO) agreements and the TPP is *the first* international agreement to have such a Chapter. This Chapter expressly promotes regulatory cooperation arguing for the "use of good regulatory practices in the process of planning, designing issuing, implementing and reviewing regulatory measures in order to facilitate achievement of domestic policy objectives, and in efforts across governments to enhance regulatory cooperation."[247] The use of good regulatory practices includes performing 'impact assessments" when developing proposed covered regulatory measures, that "examine feasible alternatives" and their "costs and benefits" – in essence, this means adopting notice and comment procedures, enhanced stakeholder participation, access to information and mutual consultation.[248] A Committee on Regulatory Coherence is to be formed and cooperation encouraged

244 *Novel Foods: MEPs Call for Moratorium on Nano-Foods and Labelling of Cloned Meat*, European Parliament News (Nov. 25, 2014), http://www.europarl.europa.eu/pdfs/news/expert/infopress/20141125IPR80424/20141125IPR80424_en.pdf [https://perma.cc/HC4Z-2CQL] (explaining that "MEPs nonetheless amended the text and proposed a moratorium on the use of nanomaterials in food, based on the precautionary principle. They also added provisions for compulsory labelling of cloned food products").

245 *See* TPP SPS, *supra* note 234, at ch. 7, art. 7.17 (outlining the Cooperative Technical Cooperations procedures).

246 *See* Trans Pacific Partnership ch. 25, Feb. 4 2016 [Hereinafter TPP RC] [https://perma.cc/2YKS-EDQG] (announcing the regulatory coherence provisions of the TPP).

247 *Id.* at 25.2(1).

248 *Id.* at 25.5(2).

and strengthened through "information exchanges, training programs, and other relevant activities between regulatory agencies".[249] These may allow parties to resolve frictions earlier, before a regulatory dispute escalates. Third, the TPP includes a Market Access Chapter, which includes a section on bioengineering and additives[250] —areas which have been ripe for regulatory collisions. In light of complaints (from the European Union) over trade in genetically modified organisms, the United States drafted language in the TPP to preempt any future complaints from countries espousing similar views as the European Union in this realm. Finally, another Chapter entitled, "Trade in Products of Modern Biotechnology", notes that products derived from agricultural biotechnology are grown in 28 countries, traded widely, and that the "TPP includes commitments to provide transparency on government measures on biotechnology trade".[251] It also provides for information sharing and procedures for Parties to follow when the low-level presence of biotech material is detected in a shipment of agricultural commodities or food products. [252]

Finally, the TPP contains other features to nudge countries toward regulatory cooperation. The TPP Chapter on Labor, Chapter 19, contains labor protection regulations which, if not adopted and implemented, allow the United States to withhold or suspend tariff reductions specified in the treaty.[253]

An example regarding GMOs best illustrates how these TPP features may operate. Recognizing that issues with GMOs have been raised in the WTO in the past and are a continuing concern in trade negotiations,[254] one could imagine other TPP

[249] *Id.* at 25.7(1).

[250] *See* Trans Pacific Partnership ch. 2 Feb. 2016, [Hereinafter TPP National Treatment] [https://perma.cc/2YKS-EDQG] (explaining procedures followed related to agricultural goods made using modern biotechnology).

[251] *See Id.* at art. 2.32 (outlining the transparency measures within the TPP).

[252] *Id.*

[253] *See* Trans Pacific Partnership ch. 19 Feb. 2016, [Hereinafter TPP Labor] [https://perma.cc/2YKS-EDQG] (containing a letter between U.S. and Vietnam for Enhancement of Trade and Labor Relations); *see also id.* at §V(B)(VIII) (explaining that the Review of Implementation states that the United States may withhold or suspend any TPP tariff reductions should Vietnam not uphold labor liberalization provisions).

[254] *See US Officials 'Disappointed' the EU Wants to Let Member States Decide Whether to Allow GMO Products*, BUS. INSIDER (Apr. 24, 2015), http://www.businessinsider.com/afp-us-says-new-eu-plan-for-gmo-imports-is-no-solution-2015-4 [https://perma.cc/M385-VGWA] (noting EU proposal to allow the 28 member states to individually decide whether to allow the import of

Members requiring labeling of GMOs in food (following the European Union precautionary principle model). A TPP Member could raise a concern with GMO labeling rules in another TPP Member by invoking the TPP SPS Agreement, under the 'Cooperative Technical Consultations' provision.[255] This same issue could also be raised in the TPP Market Access Chapter, under the section on "products of biotechnology" which establishes a mechanism for importing countries to decide on product safety and establishes a working group for the topic.[256] However, even before a Member country implements a new rule, countries are to inform each other of new rules under the Regulatory Coherence Chapter and a Committee on Regulatory Coherence will review impact assessments and cost benefit analyses. In this way, regulatory cooperation takes place before and after rule-making through special cooperative committees, and even then, in some cases (labor) treaty benefits are rescinded before the onset of a trade dispute under the dispute settlement provisions in the TPP Agreement or under the WTO.

While Mega-Regionals represent an evolution towards more regulatory cooperation, positive and negative externalities are inevitable.

5. EXTERNALITIES

While mechanisms aimed at cooperative regulation result in positive externalities, such as regulatory coherence, there are potential negative externalities, such as limits to policy space and scientific examination.

5.1. Positive Externalities

Regulatory coordination, marked by the use of harmonization, standard-setting, and recognition of equivalence has several potential benefits. Regulatory cooperation has the potential to reduce

genetically modified organisms or food, animal feed and other products made with them).

255 *See* TPP SPS, *supra* note 215, at ch. 7, art. 17 (outlining the protocols and procedures countries must follow regarding sanitary and phytosanitary measures).

256 *See* TPP National Treatment, *supra* note 252, at ch. 2.

regulatory collisions and imminent collisions in the WTO. It also has the potential to raise standards not only within the TPP but beyond the TPP by encouraging exports from Regional Trade Agreement-based firms to nations outside of the agreement.[257] One example of this is the European Union's Global System for Mobile Communications standard.[258] When 300 million European consumers embraced this standard, many non-European Union nations embraced it as well. Developing countries adhere to standards that are more appropriate to wealthier counterparts. Regulatory coherence aided Nokia and other European Union firms to compete in developing countries and overall, it helped European Union firms win the global standards competition.

Generally, regulatory coherence spanning geographic areas the size of the TPP tends to spill over into countries outside of the agreement. For example, Switzerland and Norway are not members of the European Union but adopted European Union Single Market standards as they emerged.[259] In food safety, harmonization has led to many benefits such as enhanced trade, possible enhanced food safety, and again, positive spillovers to countries outside of the agreement.

5.2. Negative Externalities

Five negative externalities related to IRC deserve mention, such as limiting regulatory innovation, restricting transparency, fostering technoimperialism, and moving away from the scientific standard.

First, international regulatory harmonization at the level of nation-states may be unattainable or undesirable[260] based on several

[257] *See* Joseph Francois et al., *Reducing Transatlantic Barriers to Trade and Investment: An Economic Assessment*, Study for the European Commission, CEPR REPORT (2013) (assessing the impact of reduced trade barriers on TPP nations and third nations like Indonesia).

[258] *See Mobile Technology GSM,* EUROPEAN TECH. STANDARDS INS. (2016) http://www.etsi.org/technologies-clusters/technologies/mobile/gsm [https://perma.cc/8LCE-SEF3] (providing a definition of the Global System Communication Standard).

[259] *See* Francois, *supra* note 257, at 29 (discussing the role of the EU as a trading partner, encouraging others to adopt its standards).

[260] *See generally* Annelise Riles, *Managing Regulatory Arbitrage: An Alternative to Harmonization in CORNELL L. FACULTY PUB. PAPER 880* (2013), http://scholarship.law.cornell.edu/

negative externalities, such as the losses to regulatory innovation, transparency, and strict scientific examination. Professor Riles argues that in financial regulation there are discrete benefits from maintaining a diverse group of inconsistent regulations.[261] Professors Weiner and Alemanno defend regulatory heterogeneity by highlighting innovation benefits.[262] Proponents of heterogeneity and the way in which IRC generates harmonized substantive regulatory requirements has been to focus IRC on less-intrusive regulatory objectives, including cooperation on regulatory impact analysis (RIA) and risk-assessment processes, and to focus on intensive consultation and information-sharing.[263]

Second, the TPP has the potential to limit transparency for some countries. The TPP involves negotiation between key economic actors—nation-states, private parties (investors), and non-governmental organizations (NGOs)—with each actor commanding influence and driving certain priorities. For a glimpse into investor priorities in the right to medicines debate, one only needs to look at the influential role of the pharmaceutical sector ("Big Pharma") in influencing the Intellectual Property Chapters of the TPP (e.g., pushing for restraining competition in the trade of biologics).[264]

Third, the negotiations involve a heterogeneous mix of developed and developing countries negotiating to meet a consensus. In the TPP, negotiations between the United States (a developed country example) and Vietnam (a developing country example) involved multiple concessions.[265] The lack of developing country input into the formation of standards translates into what some ob-

cgi/viewcontent.cgi?article=2378&context=facpub [https://perma.cc/VNT6-3UL5] (confronting the prevailing wisdom that regulatory arbitrage can be counteracted only if the rules across all legal systems are harmonized, stating that 'choice of law' can be used to address persistent regulatory differences).

261 *Id.*

262 *See* Jonathan B. Wiener & Alberto Alemanno, *The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory,* 78 L. & CONTEMP. PROBS., No. 4, 2015 (stating that regulatory heterogeneity is important for innovation—countries can experiment and be laboratories for experimentation).

263 *See* Bull et al., *New Approaches*, *supra* note 34, at 15 (discussing the use of cooperation on regulatory impact analysis as a less intrusive objective).

264 *See supra* note 115.

265 *See US–Vietnam Plan for Enhancement of Trade and Labor Relations*, Trans Pacific Partnership ch. 19 Feb. 2016 (presenting letters exchanged between the United States and Vietnam in the negotiation process).

servers have called '*technoimperialism*', or the imposition of standards by rich countries upon poor ones.[266] Finally, nations may lose their authority to regulate on public health matters due to the heterogeneity in the provisions negotiated. Agreements cover so much ground that 'a gain in one chapter' is 'a loss in another'.

Fourth, in some areas, the TPP SPS Agreement itself may provide for less working autonomy to regulate. For intellectual property protection, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) states, "Members shall be free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice."[267] The SPS Agreement is not as broad as this TRIPS Agreement provision; however, the SPS Agreement provides less autonomy to regulate from the start. When Professor Frankel asserts, "all of the international negotiations and agreements over intellectual property have the cumulative effect of curbing national autonomy that the TRIPS agreement naturally allows,"[268] the same is less relevant for the SPS Agreement. Compared to the TRIPS Agreement, there was less autonomy with the SPS from the beginning.

Fifth, the movement toward a Mega-Regional, and its many committees and consultation avenues for dispute-resolution, can be viewed as a movement away from a scientific standard (and counterintuitively towards the precautionary principle).[269] The WTO has historically been viewed as a science-based framework. And yet, there are those who see this science-based framework as overly restrictive[270] and others who argue that factors outside of

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[266] *See FAO/WHO Expert Meeting*, *supra* note 6, at 1949.

[267] *See* Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 82, 84 – 85 (1994) (providing that "members shall give effect to the provisions of this Agreement. Members may, but shall not be obligated to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.")

[268] Susy Frankel, *Eroding National Autonomy from the TRIPS Agreement, in* INT'L ECON. L. AND NAT'L AUTONOMY 114 (Meredity Kolsky Lewis & Susy Frankel eds., Cambridge Univ. Press 2010).

[269] I thank Hillary Allen for raising this point.

[270] *See* Alan O. Sykes, *Domestic Regulation, Sovereignty, and Scientific Evidence Requirements, a Pessimistic View,* 3 CHI. J. INT'L L. 353, 354 (2002) (arguing that the scientific benchmark represents undue hurtles for regulators who sincerely pursue objectives other than protectionism). *But see* Robert Hudec, *Science and Post-Discriminatory WTO Law,* 26 B.C. INT'L & COMP. L. REV. 185, 189 (2003) (discussing

science should drive regulation.[271] As Tracey Epps notes, "one of the key questions raised regarding the scientific evidence benchmark is its appropriateness in democracies where public sentiment finds a risk worthy of regulation contrary to the views of experts."[272] Any scientific process, she argues, "is in fact highly indeterminate, subjective and vulnerable to manipulation and capture by protectionist interests"[273]; science may not be the best, but it is the best we have.

6. CONCLUSIONS

In an era of emerging technologies in food production, countries want to preserve their right to regulate food safety risks. But in reality, countries operate in a free trade framework where challenges to domestic regulations in the WTO and other venues are common. In this context, countries shop for new agreements that enable them to maintain regulatory flexibility and also provide coordination of efforts internationally to ensure food safety.

This Article argues that traditional models of international regulatory cooperation are failing to provide the regulatory cooperation countries need. Mega-Regionals, with the TPP as the leading exemplar, provide a new promising mechanism for IRC and a way

the interaction between science and WTO law); Jeffery Atik, *Science and International Regulatory Convergence*, 17 NW. J. INT'L L. & BUS. 736, 758 (1997) (explaining that science can sometimes alter decision-makers regulatory actions); Vern Walker, *The Myth of Science as a Neutral Arbiter for Triggering Precautions,* 26 B.C. INT'L & COMP. L. REV. 197, 228 (2003) (demonstrating that "science can[not] serve as a 'neutral arbiter' for triggering precautionary measures."). Presumably this was in response to political pressure arising out of the aforementioned Phillip Morris case.

[271] Other critics are concerned with the apparent exclusion by the SPS Agreement of non-scientific justifications for measures, arguing that reliance on science is misplaced because it precludes any consideration of social, cultural and ethical concerns and that nations will find their sovereignty diminished if there is no space for consumer anxieties to be respected and domestic politics accommodated. *See* Dayna Nadine Scott, *Nature/Culture Clash: The Transnational Trade Debate Over GMOs 42* (New York: Hauser Global Law Program, Global Law Working Paper 06/05, 2005) (arguing that factors other than science should drive regulation); *see also* Walker, *supra* note 270, at 225 ("Non-scientific decisions are inherent in the findings about risk needed to justify precautionary measures under the SPS Agreement").

[272] Epps, *supra* note 134, at 299.

[273] *Id.*

to achieve higher food safety outcomes.

The TPP provides new mechanisms to help complete the 'wish list' for regulatory cooperation, carries forward best practices from prior agreements such as "WTO-*plus*" features that go beyond the protections in the WTO agreement, and introduces other novel features that raise food safety. Innovations include a new due process panel, the 'SPS Technical Consultation' feature, a 'Regulatory Coherence' Chapter with an explicit call to encourage regulatory cooperation, and a Market Access Chapter with special provisions addressing cooperation with respect to trade in biotechnology and food additives. Through provisions and Chapters, the TPP provides for more regulatory cooperation—facilitating dialogue, information sharing, deliberative processes, consultation, international standards, mutual recognition agreements—in ways that will raise food safety.

While positive spillovers are likely to include adoption of higher standards to facilitate trade with Mega-Regional Members, and higher standards with countries outside of the agreement, negative externalities such as losses to regulatory innovation, transparency and strict scientific examination, are noted. This is important as new agreements, provisions, and chapters, will be modeled after the TPP; a glimpse into the negotiations on the China-Australia Free Trade Agreement reveals many provisions, including safeguards to protect Australian labor upon Chinese investment, similar to those found in the TPP.[274]

Addendum: *Since the inception of this Article, we have witnessed a noteworthy shift toward widespread popular discontent with the institutions of international economic law, and their role in globalization. Recent events show that in the United States and Europe, the future of trade agreements is in doubt. In the United States, the Trans-Pacific Partnership talks are stalled with President-elect Donald Trump promising to withdraw the United States from TPP on his first day in office, and in Europe, 'Brexit' talks are escalating. While this tumultuous time may be difficult for international economic lawyers, it also represents an opportunity to openly discuss new agreements such as the Trans-Pacific Part-*

[274] See Australian Lawmakers Review Possible Compromise for China Trade Deal Ratification, INT'L CTR. FOR TRADE AND SUSTAINABLE DEV., Bridges, Volume 19, number 32. (Oct. 15, 2015), http://www.ictsd.org/sites/default/files/review/bridgesweekly19-34.pdf [https://perma.cc/6BC3-XWE4] (announcing proposed changes to Australia's Migration Act).

nership—balancing their strengths alongside their weaknesses. Looking forward, this Article provides policymakers with a way to view the Trans-Pacific Partnership, and others agreements like it—as vehicles aimed at cementing high standards on controversial issues related to food safety, across an increasingly important regional value chains, using new mechanisms for regulatory cooperation.

APPENDIX

Table 1: SPS Disputes

WTO Case	Case Description
EC-Hormones	A complaint by the United States and Canada regarding the European Union ban on meat treated with growth promoting hormones.
Australia-Salmon	Complaints by the United States and Canada against Australia's restrictions on imports of fresh, chilled or frozen salmon.
Japan-Agricultural Products II	A United States complaint to examine Japan's requirement that each variety of certain fruits be tested with regard to the efficacy of fumigation treatment.
Japan-Apples	A United States complaint to examine Japan's restriction on apples due to 'fire blight'.
Australia-Fresh Fruit and Vegetable	A Philippines complaint to examine Australia's quarantine procedures.
Australia-Quarantine Regime	Complaints by the European Union against Australia's quarantine procedures.
EU-Biotech	Complaints by the United States, Canada and Argentina concerning European Community measures affecting the approval and marketing of biotech products.
US-Continued Suspension	Complaints by the European Community against the United States and Canada on their continued suspension of obligations relating to the EC-Hormones dispute.
Australia-Apples	A New Zealand complaint to examine Australia's restrictions on apples.

US-COOL	Complaints by Canada and Mexico regarding the United States on the Certain Country of Origin Labeling Requirements.
US-Poultry	A Chinese complaint to examine United States measures affecting imports of poultry.
Korea-Bovine Meat (Canada)	A Canadian complaint to examine Korea's measures affecting the importation of bovine meat and meat products.

Table 2: International Regulatory Cooperation Techniques

Technique	**Description**	**Food Safety Example**
1.) Fully Uncoordinated Regulatory Heterogeneity	--	--
2.) Dialogue	Informal exchange of information to foster mutual understanding	Transatlantic Economic Council, Infosan
3.) Procedural Soft Law	Cooperation among states based on non-legally binding instruments	OECD guidelines and principles, Global Salm-Surv, OZFoodNet, Infosan
4.) Private codes	Coordinated technical standards adopted by multinational private standards organizations	GlobalGAP, International Standards Organization (ISO)
5.) Intergovernmental Reliance on Private Codes	The incorporation of international private codes into national legislative instruments	Global Food Safety Initiative, in the FSMA rules
6.) Transgovernmental Networks	Cooperation among agencies or units of national governments	Global Salm-Surv,

	based on frequent interaction by peers (not treaties)	
7.) Mutual Recognition Agreements	In national regulatory law retaining different national standards but agreeing to allow market access upon approval by the other jurisdiction's regulatory authority	US-China Equivalence agreement with on Poultry
8.) International Agreements	Multilateral accords to reduce regulatory barriers to trade	WTO
9.) Membership in International Organizations	Promote regulatory cooperation	Codex
10.) Formal Regulatory Partnerships	Formal arrangements	US-Canada Regulatory Cooperation Council
11.) Integration and Harmonization Through a Given supranational/Joint Institution	Agreement to adopt the same regulatory standard in each national regulation	U.S. federal legislation on food safety applied through member states. Or EU Directives.
12.) Joint Regulator	A single regulatory agency to promulgate joint regulations with standards covering two or more jurisdictions	The Joint Food Standards Australia and New Zealand
13.) A Single Global Regulatory Law	--	--

Source: Column 1 & 2, Reeve Bull et al; Column 3, Brunet Marks