Mengyi Wang & Ching-Fu Lin, Towards a bottom-up SPS cooperation: An analysis of regulatory convergence in food safety regimes 8(1) TRADE L. & DEV. 117 (2016)

Towards a Bottom-up SPS Cooperation: an Analysis of Regulatory Convergence in Food Safety Regimes

MENGYI WANG* & CHING-FU LIN[±]

Over the past two decades, under the general framework of the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement") of the World Trade Organization ("WTO"), countries have devised and revised their food safety laws in an uncoordinated fashion. As a result, a fragmented global food safety governance now stands in contrast to an increasingly globalized food supply chain. Nevertheless, the latest wave of updates of food safety regimes in the United States, the European Union, and China points to several nodes of convergence. This paper elaborates on these converging themes, including their boundaries, and explores the policy implications. It suggests that these unifying themes are areas ripe for international cooperation, a roadmap for other countries' legal update, a best practice to be diffused for enhanced global food safety, and a call for additional civil society participation.

TABLE OF CONTENTS

- I. INTRODUCTION
- II. REGULATORY LANDSCAPE
- III. NODES OF REGULATORY CONVERGENCE
- IV. THE BOUNDARIES OF CONVERGENCE
- V. POLICY IMPLICATIONS
- VI. CONCLUSION

I. INTRODUCTION

^{*} Senior Legal Fellow, New Markets Lab; J.D., Harvard Law School, mewang@jd15.law.harvard.edu.

[±] Assistant Professor of Law, National Tsing Hua University, Taiwan; S.J.D., LL.M., Harvard Law School; chingfulin@mx.nthu.edu.tw.

The authors are indebted to Mark Wu, Robert Z. Lawrence, and Marisa Goldstein for their generous mentorship.

Despite the growing globalization of food supply chain, the global food safety governance is fractured by national laws and regulations. Indeed, multilateral and regional disciplines set out the overarching framework but are limited in scope and depth. Under the rubric of the SPS Agreement¹ of the WTO and SPS-Plus provisions in regional trade agreements,² divergent national food safety regimes have flourished.

Yet beneath this disunity lies notable unity. The recent wave of sweeping modernization of food safety regimes in the world's largest food traders—the United States, the European Union, and China³—displays a number of converging themes: the paradigm shift from a reaction to prevention-based system, the switch from a sectional to an integrated supply-chain approach, the ascending prominence of science, and the increasing responsibility of private actors. Importantly, the extent of harmonization of food safety systems is confined by their distinct national legal systems, regulatory philosophies, risk perceptions, industry and market structures, and development stages.⁴

This paper outlines the regulatory convergence among the United States, the European Union, and China and expounds on key policy implications. In particular, these shared characteristics present obtainable goals for further

¹ Agreement on the Application of Sanitary and Phytosanitary Measures, Annex 1A, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 59 (2000), 1867 U.N.T.S. 493 (1994) [hereinafter SPS Agreement]. See generally LUKASZ GRUSZCZYNSKI, REGULATING HEALTH AND ENVIRONMENTAL RISKS UNDER WTO LAW: A CRITICAL ANALYSIS OF THE SPS AGREEMENT (2010); JOANNE SCOTT, THE WTO AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES: A COMMENTARY (2007); Gabrielle Marceau & Joel P. Trachtman, The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tariff and Trade: A Map of the World Trade Organization Law of Domestic Regulation of Goods, 36 J. WORLD TRADE 811 (2002).

² Jackson and Vitikala have reviewed 256 regional trade agreements (RTAs) currently in force and identified all the SPS-plus provisions therein vis-à-vis those stipulated in the SPS Agreement. For their comprehensive survey, see Lee Ann Jackson & Hanna Vitikala, *Cross-Cutting Issues in Regional Trade Agreements: Sanitary and Phytosanitary Measures, in* REGIONAL TRADE AGREEMENTS AND THE MULTILATERAL TRADING SYSTEM 316 (Rohini Acharya ed., 2016).

³ Based on available statistics from 2014, EU, US and China were the largest international traders of food products based on the combined value of food exports and imports. *See* International Trade Statistics 2015, WTO, 81,

https://www.wto.org/english/res_e/statis_e/its2015_e/its2015_e.pdf.

⁴ Cf. Bernd van der Meulen, *The Global Arena of Food Law: Emerging Contours of a Meta-Framework*, 3(4) ERASMUS L. REV. 217 (2010).

international cooperation. Furthermore, the trend-spotting analysis of this paper could serve as a useful roadmap and template for other countries interested in updating their food safety systems. Additionally, the positive spillover of these common threads should prompt the three economies to encourage and facilitate the uptake of the unifying practices. Finally, the convergence lays bare the inadequacy of civil society participation.

This paper is organized as follows: Section I sketches the current international disciplines and decentralized food safety regulations in the context of growing food trade. Section II articulates the specific nodes of regulatory convergence of the United States, the European Union, and China observed through their recent legislative and institutional reform. Section III qualifies the extent of ultimate harmonization by discussing the boundary and limiting factors of these convergences. Section IV concludes by exploring the policy implications of the analysis for food safety governance.

II. **REGULATORY LANDSCAPE**

A growingly globalized and sophisticated system of food trade has emerged in the absence of global food safety governance. With shallow multilateral and regional integration, the global food safety landscape is heavily fractured by national laws and regulations. This section outlines the multilateral framework that lays down baseline rules for national regulations and leaves abundant room for regulatory discretion.

Multilaterally, the linchpin of global food safety governance is the SPS Agreement. As a trade treaty, the SPS Agreement seeks to balance trade liberalization and national regulatory autonomy. That is, on the one hand, the SPS Agreement aims to remove behind-the-border trade barriers and to promote harmonization.⁵ On the other hand, it allows WTO Members to preserve substantial regulatory freedom by setting the appropriate level of protection ("ALOP") against a given risk and craft their measures accordingly.⁶

More specifically, several obligations govern the enactment and maintenance of food safety regulations. First, food safety regulations must either be based on

⁵ See, e.g., SPS Agreement, supra note 1, Article 3; Appellate Body Report, EC – Measures Concerning Meat and Meat Products (Hormones), WT/DS26/AB/R, WT/DS48/AB/R (adopted 13 February 1998) ¶ 177 [hereinafter EC – Meat Products].

⁶ See, e.g. SPS Agreement, *supra* note 1, Annex A(5); Appellate Body Report, *India – Measures Concerning the Importation of Certain Agricultural Products*, WT/DS430/AB/R (adopted 19 June 2015) ¶ 5.76.

120 117

international standards or risk assessment.7 Second, in conducting risk assessment, a Member must take into account a number of scientific and economic factors, including available scientific evidence and "the costs of control or eradication in the territory of the importing Member."8 As an exception to the risk assessment requirement, in situations where relevant scientific evidence is insufficient, a government may take precaution and provisionally adopt SPS measures on the basis of available information.⁹ Third, while it is the prerogative of each WTO Member to delineate its ALOP, a Member must ensure consistency of ALOPs by avoiding "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."10 Fourth, regulations expressing ALOPs must be least trade-restrictive.¹¹ Other important aspects of the SPS Agreement include harmonization through international standards, guidelines or recommendations,¹² recognition of *equivalence* upon demonstration of the achievement of the importing Member's ALOP,13 and adaptation to regional conditions.14

Importantly, these obligations under the SPS Agreement are formulated at high levels of generality, and existing WTO jurisprudence is yet to define the contours of the obligations. As a result, with ample policy space in the food safety arena, WTO Members have built largely uncoordinated national regulatory schemes.

Giving expression to the regulatory autonomy embedded in the SPS Agreement, the world's largest food traders have in recent years instituted extensive legislative and institutional reforms. Triggered by a series of food safety outbreaks, the European Union adopted the General Food Law with the intent to create a single, transparent set of EU food safety rules applicable to all food and feed products.¹⁵ The EU General Food Law established the European Food Safety Authority

⁷ SPS Agreement, *supra* note 1, Articles 3, 5.

⁸ *Id.*, Articles 5.1, 5.2, Annex 4.

⁹ *Id.,* Article 5.7, Annex 4; See Appellate Body Reports, *US/Canada — Continued Suspension*, WT/DS321/AB/R (adopted 16 October 2008) ¶ 677.

¹⁰ SPS Agreement, *supra* note 1, Article 5.5; *EC – Meat Products, supra* note 5, ¶ 214.

¹¹ SPS Agreement, *supra* note 1, Article 5.6; See Appellate Body Report, *Australia - Measures Affecting Importation of Salmon*, WT/DS18/AB/R (adopted 20 October 1998) ¶ 194.

¹² SPS Agreement, *supra* note 1, Article 3; See *EC – Meat Products*, ¶ 177.

¹³ SPS Agreement, *supra* note 1, Article 4.1.

¹⁴ Id., Article 6; See EC – Meat Products, supra note 5, ¶¶ 5.131-133.

¹⁵ Council Regulation 178/2002 Laying Down the General Principles and Requirements of Food Law, 2002 O.J. (L 31) 1 [hereinafter EU General Food Law]. For a comprehensive introduction to the EU General Food Law, see ALBERTO ALEMANNO, TRADE IN FOOD: REGULATORY AND JUDICIAL APPROACHES IN THE EC AND THE WTO 73–223 (2007).

("EFSA") and a number of general principles, detailed requirements and procedures on food safety regulation. The General Food Law covers all stages of the food-production chain, adequately emphasizes consumer health protection, and mandates a single authority that serves as the scientific reference point for the European Union. In 2014, the European Commission further promulgated Smarter Rules for Safer Food, a set of regulations that streamlines the legal framework for food safety¹⁶ Similarly, food safety regulation in the United States has been transformed by the Food Safety Modernization Act ("FSMA")17, which was signed into law by President Obama in January 2011, aiming to revamp the outdated set of provisions in the Federal Food, Drug, and Cosmetics Act ("FFDCA") promulgated in 193818 and the Pure Food and Drug Act in 1906.19 FSMA brings major reforms to the FFDCA and expands the FDA's authority.²⁰ Likewise, spurred by a string of high profile food safety scandals, China has taken pains to retool its food safety regime. The centerpieces of the reform are the redesign of institutional framework in 2013 and the amendment of the Food Safety Law (2009) in 2015. The China Food and Drug Administration ("CFDA") and an array of supporting agencies, such as the Ministry of Agriculture, are tasked with rolling out implementing regulations and additional standards.

III. NODES OF REGULATORY CONVERGENCE

As food safety regimes evolve in these three markets, four nodes of regulatory convergence can be discerned. These converging mandates and methodologies in the design and underlying rationale of the three legal frameworks include the paradigm shift from reaction to prevention-based systems, the switch from sectional to integrated supply-chain approach, the ascending prominence of science, and the increasing responsibility of private actors. As we will explain later in the policy implication section, these unifying attributes may serve as a shared language and a compatible premise for some level of international cooperation within and beyond this club.

Smarter rules for safer food: Commission proposes landmark package to modernise, simplify and strengthen the agri-food chain in Europe, EUROPEAN COMMISSION, http://europa.eu/rapid/press-release_IP-13-400_en.htm.

¹⁷ Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) [hereinafter FSMA]. For an introduction, *see, e.g.*, Debra M. Strauss, *An Analysis of the FDA Food Safety Modernization Act: Protection for Consumers and Boon for Business*, 66 FOOD DRUG L.J. 353 (2011).

¹⁸ Federal Food, Drug, and Cosmetics Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

¹⁹ Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906).

²⁰ Margaret A. Hamburg, Food Safety Modernization Act: Putting the Focus on Prevention, at http://www.whitehouse.gov/blog/2011/01/03/food-safety-modernization-act-putting-focus-prevention.

117 1. Paradigm Shift from a Reactive to a Preventive Approach

The first node of convergence is the paradigm shift from a reaction-based to a prevention-based approach. For instance, while China has not expressly established its model of risk prevention in a detailed fashion, the principle is enshrined in Article 3 of China's Amended Food Safety Law and finds expression throughout the new law. Indeed, instead of relying exclusively on end-product testing and other reactionary approaches such as recall, the new law seeks to minimize or prevent risks by control at the different points of food production and distribution, such as during agricultural input, processing, transportation, distributors to "regularly inspect the implementation of preventive measures related to food safety" and to eliminate potential food safety risks in a timely manner.²² Additionally, the new law also encourages the implementation of Hazard Analysis and Critical Control Points ("HACCP"),²³ which identifies potential hazards to be controlled and serves as a preventive risk management tool.

Likewise, in the United States, Title I of FSMA, "Improving Capacity to Prevent Food Safety Problems,"²⁴ expounds on a preventive approach. More specifically, FSMA requires food facilities - from manufacturers, processors, packers, to distributors - to adopt a hazard analysis and risk-based methodology of prevention.²⁵ Food facilities are required to evaluate their production or handling process and identify hazards that are known or reasonably likely to occur. These hazards include: "biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, and unapproved food or color additives."²⁶ To prevent or minimize the likelihood of such hazards, food facilities are further required to devise written preventive control plans that pinpoint critical control nodes. Controls such as "sanitation, training, environmental controls, allergen controls, a recall contingency plan, Good Manufacturing Practices ("GMPs"), and supplier verification activities"27 will also be closely implemented. Under such a prevention-based framework, the FDA has to depart from its traditional approach of inspection and reaction to further work proactively with the food industry in preventing food safety problems.

²⁷ Id.

²¹ See, e.g., Food Safety Law of the People's Republic of China (2015), Articles 33, 56 [hereinafter Amended Food Safety Law].

²² Id., Article 102.

²³ *Id.*, Article 48.

²⁴ FSMA, *supra* note 17, Title I.

²⁵ Id., Title I §103.

²⁶ Id.

The EU General Food Law requires the food industry to bear the primary responsibility for ensuring food safety,28 which may be implemented in varied ways. Pursuant to the objectives laid down by the EU General Food Law, the European Parliament and the Council of the European Union adopted Regulation (EC) No 852/2004 on the Hygiene of Food Stuffs in 2004, which explicitly mandates preventive HACCP measures in specific sectors (e.g. plant products, animal and animal products, and production facilities).29 According to the principles set forth in Article 1 of the Regulation, "general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility."³⁰ The Regulation further asks the European Commission as well as member states to develop, disseminate, and use guidelines to facilitate the implementation of HACCP principals so as to prevent and mitigate foodborne hazards.³¹ The adoption of this Regulation indicates the European Union's regulatory orientation to process control rather than end-product control.³² While the European Union leaves ample room for local, regional, and national authorities to adopt, implement, and monitor HACCP-related activities,33 the methodological shift from reaction to prevention is clear.

2. Sectional to Supply-chain Approach

The second node of convergence is the holistic supply-chain approach. The supply-chain approach emerged as a necessary response to the changing terrain of food trade. The intense economic globalization of the past several decades has made national boundaries permeable for the flow of goods, services, humans, investment, and information.³⁴ The rapid advancement of food science and transportation technology, the advent of the WTO and its agreements aimed at trade liberalization, and the growth of transnational agri-food corporations have

²⁸ EU General Food Law, *supra* note 15, art. 17.

²⁹ European Parliament and Council of the European Union, Regulation (EC) No 852/2004 on the Hygiene of Food Stuffs, (OJ L 139, 30.4.2004, preamble; arts. 1, 5, 7, and 9; Annexes I, II, V, IX, and XI.

³⁰ *Id.*, Article 1(d).

³¹ *Id.*, Articles 7-9.

³² Lotte Holm & Bente Halkier, EU Food Safety Policy: Localising Contested Governance, 11(4) European Societies 473, 479 (2009).

³³ Ladina Caduff1 & Thomas Bernauer, Managing Risk and Regulation in European Food Safety Governance, 23(1) Review of Policy Research 153, 160-61 (2006).

³⁴ Yasmine Motarjemi et al., *Future Challenges in Global Harmonization of Food Safety Legislation*, 12(6) FOOD CONTROL 339, 340-41 (2001); Fritz K. Käferstein et al., *Foodborne Disease Control: A Transnational Challenge*, 3(4) EMERGING INFECTIOUS DISEASES 503, 503-10 (1997).

¹¹⁷ made global sourcing of food ingredients feasible.³⁵ Consequently, the global food supply chain has also been extended. The globalization of food production, distribution, and consumption means no single State can ensure its food safety on its own in such an interdependent world.³⁶ Indeed, problems caused by the regulatory failure of one country can spill over to others with serious consequences for the latter's public health.³⁷ A weak national public food safety governance institution can have wide-reaching implications, which necessitates the design of a holistic supply-chain approach to food safety regulation.

Consequently, the United States, the European Union, and China have all adopted regulatory schemes that focus not only on sectional inspections in the conventional manner but also on the entire supply chain. This is evidenced by a combination of legislative and institutional reforms. The all-embracing EU General Food Law's "farm-to-fork" design covers all stages of food production, distribution, and consumption, strengthened by a supply-chain traceability mechanism.³⁸ The preamble to the EU General Food Law highlights the necessity to incorporate "all aspects of the food production chain as a continuum ... because each element may have a potential impact on food safety."39 More specifically, a supply chain approach covers from, inter alia, production, processing, transport, distribution, import, and export to consumption.⁴⁰ Complementing the EU General Food Law that applies to all stages of the supply chain,⁴¹ a comprehensive traceability system is in place to keep track of "food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed."42 The traceability system established by the EU can serve as a mechanism to generate a steady flow of information, which allows member states (and even external stakeholders) to retrieve the complete history of a food or feed product at any point along the supply chain so as to take risk management measures if necessary.43 Some perceive the EU General Food Law's supply chain and traceability mechanisms as essentially a precautionary and procedural approach to food safety regulation; others regard such mechanisms as a means to disclose

³⁵ See generally Ching-Fu Lin, Global Food Safety: Exploring Key Elements for an International Regulatory Strategy, 51(3) VA. J. INT'L L. 637, 661-63 (2011). [hereinafter Lin (2011)]

³⁶ Id.

³⁷ Id.

³⁸ Id.

³⁹ EU General Food Law, *supra* note 15, preamble, para. 12.

⁴⁰ *Id.* preamble, paras. 13, 14, and 29.

⁴¹ *Id.* Article 1.3.

⁴² *Id.* preamble, para. 28; Articles 3.15 and 18.1.

⁴³ Alberto Alemanno, The European Food Import Safety Regime Under a "Stress Test:" The Melamine Contamination of the Global Food Supply Chain, 3(4) Erasmus Law Review 203, 211 (2010).

information to consumers and therefore facilitate informed purchase choices.⁴⁴ All in all, the EU supply chain approach to food safety regulation is well defined by the law, and traceability undergirds the overall regulatory effectiveness.

An institutional overhaul brought about in 2013 exemplifies China's adoption of an integrated supply-chain approach. This reform established a framework of four key ministries that centered around CFDA and supported by an array of entities. It signals a marked departure from its previous production-step control system with authorities split across multiple ministries.⁴⁵ The founding of the CFDA marks an era of centralized vertical management of the supply chain: the Ministry of Agriculture (MOA) is responsible for the supervision and management of edible agricultural products, and CFDA takes over upon their processing or circulation in the market.⁴⁶ Importantly, parallel institutional reform at sub-national levels is also ongoing at varying paces across different levels of governance.⁴⁷

FSMA also bases its oversight system upon the global supply chain and stretches its requirements to farmers, manufacturers, processors, packers, distributors, and retailers along the chain.⁴⁸ More specifically, stringent cross-border oversight is a crucial tool of the supply-chain approach. In the United States, FSMA obligates importers to mandate their overseas suppliers to meet US food safety rules and standards.⁴⁹ In particular, FSMA mandates the Foreign Supplier Verification Program, where importers have the responsibility to undertake risk-based verification to ensure that their foreign suppliers supply food that is produced to the same standards as those required by FSMA.⁵⁰ A similar requirement is found in Chapter 6 of China's amended Food Safety Law. Imported foods, food additives, and food-related products must comply with China's national food safety standards.⁵¹ In cases where relevant standards do not exist, the overseas exporter/producer or its entrusted importers must seek approval by the National

⁴⁴ Alessandro Arienzo et al., The European Union and the Regulation of Food Traceability: From Risk Management to Informed Choice?, in Ethical Traceability and Communicating Food 23, 24 (Christian Coff et al. eds., 2008).

⁴⁵ Katrin Kuhlmann, Mengyi Wang, and Yuan Zhou. *China Food Safety Legal and Regulatory Assessment*. Syngenta Foundation for Sustainable Agriculture, 1, 2017 <u>https://www.syngentafoundation.org/sites/g/files/zhg576/f/china food safety -</u> <u>legal framework 2.pdf</u>. [hereinafter Kuhlmann et al. (2017)]

<u>legal framework 2.pdf</u>. [hereinafter Kunimann et al. (201 46 *Id.* at 3

⁴⁷ *Id.* at 5

⁴⁸ See e.g. FSMA, supra note 17, §§ 202, 204, 301.

⁴⁹ See Id., Title III.

⁵⁰ *Id.,* § 301; Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, FDA, 21 CFR 11, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm.

⁵¹ Amended Food Safety Law, *supra* note 21, Article 92.

117

Health and Family Planning Commission, the food standard setting agency, by submitting a relevant national, regional, or international standard of the exporting country (region).⁵²

Additionally, traceability is another pillar of the supply-chain approach. For instance, the amended Food Safety Law now mandates the establishment of private (food producers and distributors) and public traceability systems.⁵³ Private sector actors are encouraged to deploy information technology in designing their traceability programs,⁵⁴ and the State is slated to build a national traceability system.⁵⁵

3. Prominence of Science

The third node of convergence is the growing recognition and prominence of a science-based framework for risk regulation. It has long been argued that the work of the US FDA is mostly science-based, while the EU system is less science and more precaution-oriented.⁵⁶ However, ten years of work by the EFSA as the scientific point of reference has largely strengthened the scientific dimension of the EU risk regulation. The EFSA was established in January 2002 in accordance with the EU General Food Law to serve as an objective, independent, and scientific reference point.⁵⁷ Indeed, the EFSA is mandated to "provide scientific advice and scientific and technical support for the [EU] legislation and policies in all fields which have a direct or indirect impact on food and feed safety."⁵⁸ In practice this means that the EFSA furnishes the European Commission (EC) as well as the European Union (EU) member states with scientific advice that they take into account when forming regulatory measures in food safety areas.⁵⁹ Moreover, the EFSA performs risk assessment and risk communication.

⁵² *Id.*, Article 93.

⁵³ *Id.*, Article 42.

⁵⁴ Id.

⁵⁵ Id.

⁵⁶ See, e.g., THOMAS BERNAUER, GENES, TRADE AND REGULATION: THE SEEDS OF CONFLICTS IN FOOD BIOTECHNOLOGY 1-2 (2003); Mark A. Pollack, A Truce in the Transatlantic Food Fight: The United States, the European Union, and Genetically Modified Foods in the Obama Years (Working Paper, July 2013), at 2, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2295197. [hereinafter BERNAUER (2003)]

⁵⁷ EU General Food Law, *supra* note 15; BERND VAN DER MEULEN & MENNO VAN DER VELDE, EUROPEAN FOOD LAW HANDBOOK 253-82 (2008).

⁵⁸ EU General Food Law, *supra* note 15, Article 22.2.

⁵⁹ Alberto Alemanno, *The European Food Safety Authority at Five*, EUR. FOOD & FEED L. REV. 1, 2-24 (2008).

In the same vein, science features increasingly prominently in the latest regulatory reform in China. Nationally, the establishment of China National Center for Food Safety Risk Assessment ("CFSA") as the key technical plank in 2011 is emblematic of the trend. The key functions of CFSA speak to the dimensions of the application of science in China's food safety regime: CFSA provides technical support and guidance for risk surveillance, assessment and communication, guides and supports emergency response, and sets and consolidates national food safety standards.⁶⁰ Furthermore, the amended Food Safety Law expressly fortifies the importance of scientific evidence in a number of areas, including risk assessment at national and local levels into biological, chemical, and physical hazardous factors,⁶¹ standard setting,⁶² the regulation of healthcare food and infant formula,⁶³ investigations of food safety incidents,⁶⁴ and food testing.⁶⁵

4. Growing Importance and Responsibility of Private Actors

The fourth node of convergence is the primacy of private responsibilities. Indeed, cognizant of the limited administrative capacity, resources and expertise of regulators, and the push for technological advancement, the three economies have all endeavored to facilitate the institutionalization of private regulatory mechanisms by industry actors in ensuring food safety throughout the global supply chain. Turning first to the United States. FSMA imposes several new requirements on the industry. FSMA emphasizes the need for the FDA to revamp its food safety regulatory mechanism by partnering with private entities. Recognizing the FDA's limited administrative capacity as well as the resources, expertise and primary responsibility of the food industry. Title I of FSMA, "Improving Capacity to Prevent Food Safety Problems,"⁶⁶ effectively shifts the primary responsibility of preventing food safety problems to the food industry.

⁶⁰ Introduction, China National Center for Food Safety Risk Assessment, http://www.chinafoodsafety.net/Singel.aspx?

^{\=089}BC3C676E66C69ED579F05E01E2A89E4965ECFE6840A04&code=02B6EB4E28 3B8EBA17E90C4149F69C4D94A589955C768578; Microbiological Risk Surveillance of Food Safety in China, China National Center for Food Safety Risk Assessment, http://www.chinafoodsafety.net/detail.aspx?id=3E64433C5B1476EB06EC8BCD8FDA36 79A1864FC456E54613.

⁶¹ Amended Food Safety Law, *supra* note 21, Articles 17, 21, 23.

⁶² Id., Articles 18, 24.

⁶³ Id., Articles 75, 81.

⁶⁴ Id., Article 10.

⁶⁵ Id., Article 85.

⁶⁶ FSMA, *supra* note 17, Title I.

Engaging actors of the private sector often implies adopting innovative enforcement mechanisms, such as third-party auditing, certification, and testing. Title III of FSMA, rather than focusing on a small number of border inspections, requires the FDA to rely on *third-party* resources to regulate food imports. The reliance includes "third-party (usually private) auditors" who inspect and certify that certain foreign suppliers have met the US food safety requirements.⁶⁷

The reliance on the private sector can also be traced in the design of EU General Food Law.⁶⁸ The general principles of the EU General Food Law declare that the primary responsibility for ensuring food safety rests with the food industry.⁶⁹ European retailers and supermarkets have in turn required private food certifications of their suppliers in non-EU countries to ensure food safety.

In China, the new law departs from a formerly State-centric, command-andcontrol model and demarcates channels for private involvement in standard-setting (both governmental and industry) processes and law implementation (*e.g.* via selfdiscipline) activities. As to third-party testing, partly because CFDA usually conducts public bidding for testing services, third-party food testing has mushroomed in China.⁷⁰ The food safety testing market grew at an average rate of 20 percent from 2009 to 2012, and the value of the market is projected to USD 791.5 million by 2020.⁷¹ With respect to national standard-setting processes, trade and consumer association representatives are required to serve as members on the National Food Safety Standard Review Committee and draft national standards that must be publicly available for food producers and distributors and consumers to comment.⁷²

⁶⁷ *Id.*, Title III, Sec. 301. The FSMA also requires that importers verify that their foreign suppliers have implemented proper preventive mechanisms.

⁶⁸ EU General Food Law, *supra* note 15, Article 17.

⁶⁹ Id.

⁷⁰ New Report Published on China's Food Testing Market, QUALITY ASSURANCE & FOOD SAFETY, http://www.qualityassurancemag.com/article/new-report-published-on-china-food-testing-market. See also Kuhlmann et al, supra note 45, 14 (2017).

⁷¹ China Food Safety Testing Market & Regulations Report 2015-2020, BUSINESSWIRE, http://www.businesswire.com/news/home/20160325005111/en/China-Food-Safety-

Testing-Market-Regulations-Report; China Food Safety Testing Industry 2013 Analysis Released, QUALITY ASSURANCE AND FOOD SAFETY, http://www.qualityassurancemag.com/article/china-food-safety-testing-report/. See also Kuhlmann et al, supra note 45, 14 (2017).

⁷² Amended Food Safety Law, *supra* note 21, Article 28.

Summer, 2016] Regulatory convergence in food safety regimes 129

With respect to private standards, food industry associations are obligated to formulate and improve industry standards,73 and food production enterprises are encouraged to establish enterprise standards that are "much more" stringent than national or local standards.74 With regard to private involvement and responsibility in law implementation activities, Article 4 of the amended Food Safety Law, similar to FSMA and EU General Food Law, sets out general obligations for food producers and distributors, obligating them to ensure food safety.75 Subsequent provisions and measures elaborate on the responsibilities of stakeholders, spanning standard compliance, self-inspection, record-keeping, traceability, and training and importation. For instance, food industry associations are required to buttress industry self-discipline, provide services concerning information and technology, and educate and supervise food producers and distributors.⁷⁶ Similarly, operators of wholesale markets of edible agricultural products bear multiple responsibilities. First, as to inspection, they must have in place inspection equipment and inspectors or entrusted food inspection agencies to perform sampling inspections or fast testing.77 Second, for enforcement, they must report incidents of noncompliant products to local CFDA branches and order the trader to cease to sell.78

The ascendant responsibility of industry is also evidenced by the series of requirements imposed on importers, who must operate a review system for overseas exporters and producers, particularly in relation to standards that are absent in China, and must recall non-compliant items.⁷⁹ Moreover, importers are required to maintain an elaborate import and sale record with information such as production or import batch number.⁸⁰

IV. THE BOUNDARIES OF CONVERGENCE

Our analysis of gradual regulatory alignment may paint a picture of lock-step progression that would eventually lead to universal and comprehensive harmonization. However, this is not the case, as several disparities and difficulties seem to continue to dictate the boundaries of regulatory overlap. Many of them reflect fundamental and diverse characteristics entrenched in individual societies.

⁷³ *Id.*, Article 9.

⁷⁴ Id., Article 30.

⁷⁵ *Id.*, Article 4. *See also* FSMA, *supra* note 17, Title I; EU General Food Law, *supra* note 15, Article 17.

⁷⁶ *Id.*, Article 9.

⁷⁷ Administrative Measures for the Supervision of Markets of Edible Agricultural Products (2016), Article 8; Amended Food Safety Law, *supra* note 21, Article 64.

⁷⁸ Id.

⁷⁹ Amended Food Safety Law, *supra* note 21, Article 94.

⁸⁰ Id., Article 98.

130 117

This paper hereby points out some of these divergences that will likely persist in the future.

A chief disparity concerns regulatory culture. In particular, the United States and the European Union seem to have taken differing paths and approaches.⁸¹ Such differences have been exposed in a few controversial disputes in the WTO—such as those involving hormone-treated beef and genetically modified organisms ("GMOs").⁸² Indeed, many have argued that the significant cultural and institutional divergences between the food safety regulatory systems across the Atlantic have resulted in "regulatory polarization"⁸³ which may not be easily alleviated.⁸⁴ Cultural and culinary traditions, risk perceptions, institutional arrangements, interest group configurations, and even some incident-driven reforms are among the factors that have contributed to the divergence between the existing laws and regulations across the Atlantic. As argued by Pollack and Shaffer, the transatlantic differences are "multi-causal, lying in the ability of interest groups to capitalize on preexisting cultural and institutional differences, with an important role played by contingent events such as the European food safety scandals of the 1990s."⁸⁵

⁸¹ It should be noted here that China has embraced (or borrowed) notions of risk regulation, which have long been practiced by the United States and the European Union. For instance, China's 2009 Food Safety Law included a number of provisions on the application of risk assessment and scientific methodologies in the regulation of food safety (see 2009 Food Safety Law, Articles 11-17), the same themes are reiterated in the Amended Food Safety Law, supra note 21, Articles 3, 17, 18, 23, 85, 107. As mentioned above, the establishment and functions of CFSA, which has the Division of Surveillance and Alert, Division of Risk Assessment (I and II), and Division of Risk Communication, further notion risk regulation, reinforce the of http://www.chinafoodsafety.net/Singel.aspx?channelcode=089BC3C676E66C69ED579F 05E01E2A89E4965ECFE6840A04&code=BD5E696AD389EF56FA53494AA433E7ED3 C2CB9B10DCCDB38. Yet it remains to be seen if China has developed a discernible "regulatory culture," as the country not long ago (in 2009 and 2015) significantly revamped its food safety law and implementation is yet to be fully in place.

⁸² See Panel Reports, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R / WT/DS292/R / WT/DS293/R (adopted 21 November 2006); EC – Meat Products, supra note 5.

⁸³ In the area of biotechnology regulation, see, e.g., BERNAUER (2003), supra note 56.

⁸⁴ To some analysts, the United States and the European Union not only adopt different regulatory standards but also base their systems upon different premises of risk regulation, especially in sectors concerning biotechnology and novel foods. *See generally* MARK A. POLLACK & GREGORY C. SHAFFER, WHEN COOPERATION FAILS: THE INTERNATIONAL LAW AND POLITICS OF GENETICALLY MODIFIED FOODS (2009). ⁸⁵ *Id* at 34.

As far as food safety regulation is concerned, the US regulatory agencies seem to be more science-based, while their European counterparts are, in contrast, more precautionary, taking into account the multiple non-science concerns in the context of the EU multi-level governance structure and severe public distrust and criticism.⁸⁶ In light of this seemingly sustained divergence, many have doubted the possibility that the proposed Transatlantic Trade and Investment Partnership ("TTIP") can successfully include an SPS chapter (or an SPS-Plus chapter)⁸⁷ that strikes a proper balance between public health and international trade.⁸⁸

In addition, the variations in the underlying market structures effectively constrain the alignment of regulation. For instance, the Chinese food industry is characterized by small scale producers, with 190 million farms for crops, milk, and meat.⁸⁹ Transitioning from a largely agrarian society, a Chinese farm is, on average, 1.6 acres, which sharply contrasts with its U.S. counterpart, an average of 441 acres.⁹⁰ Furthermore, while the food industries in the European Union and the United States are highly concentrated and integrated,⁹¹ their Chinese counterpart is

⁸⁶ Simonetta Zarrilli, *International Trade in GMOs and GM Products: National And Multilateral Legal Frameworks*, UNCTAD Study Series No. 29, at 4 (2005); Mark A. Pollack & Gregory C. Shaffer, TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY 174 (2001).

⁸⁷ See 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). [hereinafter Lin (2012)]

⁸⁸ In a congressional letter in mid 2013, 76 House Members urged United States Trade Representative (USTR) Michael Froman to push for strong and enforceable SPS measures in the proposed TTIP, 76 House Members Urge Froman To Push For Strong, Enforceable SPS Measures In TPP, TTIP, INSIDE U.S. TRADE, August 26, 2013. As noted by some commentators, given the relatively low tariffs between the United States and the European Union, the chief focus of TTIP will center on reducing non-tariff barriers to trade in sectors including agricultural products, biotechnology, and food safety regulation. The US Food and Drug Administration (FDA) has also established a special public health and trade team within its Office of International Programs to take a more active role in the negotiation. See Alberto Alemanno, Towards a Transatlantic Trade and Investment Deal, available at http://www.albertoalemanno.eu/articles/towards-a-transatlantic-trade-and-investmentpartnership-ttip-the-costs-of-a-non-transatlantic-deal; FDA Takes More Active Role in TTIP TPP Talks; Establish Trade Team, INSIDE U.S. TRADE, September 5, 2013.

⁸⁹ Pricewaterhouse Coopers, *Managing Upstream Risks in China's Food Safety Chain*, 2015, http://www.pwccn.com/webmedia/doc/635766405555290452_food_supply_chain_risk_ aug2015.pdf. *See also* Kuhlmann et al, *supra* note 45, 10 (2017).

⁹⁰ Id.

⁹¹ See, e.g., Market share of the leading grocery retailers in the United States in 2014, STATISTA, https://www.statista.com/statistics/240481/food-market-share-of-the-leading-food-

retailers-of-north-america; *Competition Issues in the Food Chain Industry*, OECD, https://www.oecd.org/daf/competition/CompetitionIssuesintheFoodChainIndustry.pdf; *Global Food Industry*, UNITED STATES DEPARTMENT OF AGRICULTURE ECONOMIC

rather decentralized. Among the half a million food establishments in China, almost 80% are "cottage industries" with no more than 10 employees.⁹² Differing production scales seem highly correlated with financial incentives and capacities to comply and in turn limit the feasibility and complexity of measures in design and in practice. The design and implementation of traceability rules aptly demonstrate such ramifications, where FSMA lays down a much more nuanced and onerous requirement compared to China's amended Food Safety Law.

V. POLICY IMPLICATIONS

While identifying prominent nodes of convergence in food safety regulation in the United States, the European Union, and China, this paper does not contend that most regulatory undertakings will reach an ultimate harmonization of rules and standards. Indeed, as elaborated in the last section, limiting factors emanating from individual social and political spheres will likely persist. With these limiting factors in mind, this section argues that these converging themes nevertheless provide critical purchase in several aspects: a foundation for international cooperation, a template for other countries to update their food safety regime, a positive spillover that should be replicated to enhance global food safety, and the need to empower civil society.

First, the unifying features of food safety regimes forge the premise for fruitful international cooperation in food safety regulation. As an example, the integrated supply chain approach embraced by the three regulatory frameworks may, in turn, compel regulatory agencies to cooperate at the bilateral or multilateral level (through trade treaties or other instruments) in areas such as information exchange, certification and auditing, mutual recognition and equivalence, or laboratory collaboration. In fact, FSMA and EU General Food Law already pointedly accentuate the need for international cooperation with regulatory counterparts in other jurisdictions based on a global supply chain approach.

The ascending role of science is another case in point. The common recognition and prominence of a science-based framework for risk regulation serve as a shared regulatory language for countries to engage in constructive interactions. The use of science-based methodologies in food safety regulation is arguably the crux of the abovementioned nodes of convergence, as the institutionalization of the "language of science" is able to energize mutually-reinforcing regulatory dialogues. For

RESEARCH SERVICE, https://www.ers.usda.gov/topics/international-markets-trade/global-food-markets/global-food-industry.aspx.

⁹² Food and Agricultural Imports from China, CRS REPORT FOR CONGRESS, September 26, 2008, http://www.fas.org/sgp/crs/row/RL34080.pdf.

instance, although the legal status of the EFSA's reports (*i.e.* scientific opinions) are relatively weak due to the lack of formal authority to issue binding decisions on scientific issues (the EU merely needs to take into account the EFSA reports while making risk management decisions),⁹³ the reports can nevertheless bridge the gap between the European Union and the United States in terms of technical dialogue and information exchanges because of their common language—science.

In a case where the European Union banned US poultry imports because they were treated with pathogen-reducing chemical substance, the FDA and EFSA actually *agreed* that the US production process did not present food safety risks.⁹⁴ It seems plausible that despite divergent risk cultures and risk management measures, the level of controversy over a given food safety issue may be alleviated when both sides largely agree on the scientific level. As such, what needs further deliberation may be locating appropriate *levels* and *ways* of cooperation, either in terms of structure or substance. All in all, the shared language of science, together with the other converging themes, will likely steer the co-evolution of policy and technology, facilitate problem solving and coordination mechanisms, and generate coordinated methodological advances in the area of food safety regulation.

Second, aside from being the impetus for international cooperation, the convergence can inspire other countries to follow suit. The rationale for replicating these converging themes is two-fold. The first rationale is to increase market access in these three Members. To align one's regulatory systems with the biggest three food traders will likely improve the country's export competitiveness vis-à-vis those countries with differing food safety rules. For instance, duplicating third-party certification and auditing will help channel more food produced in one country into these three markets.

The second rationale for following these converging themes is that they may serve as best practices that countries could avail themselves of. The case study of the Philippines helps illustrate this point. As an example of recent legislative overhaul in Asia, the Philippines passed the Food Safety Act of 2013 and its Implementing Rules and Regulations in 2015. The main features of the Food Safety Act closely track the converging themes. In particular, the new law explicitly adopts a supply-

⁹³ In the EU context, the processes of risk assessment and risk management are organizationally separated, where the EFSA is in charge of the former and the EC of the latter. By contrast, the US system does not separate the two stages, as the FDA is a centralized agency in charge of risk assessment, risk management and inspections throughout the US.

⁹⁴ John F. Morrall III, *Determining Compatible Regulatory Regimes between the U.S. and the EU*, U.S. CHAMBER OF COMMERCE, at 34, available at http://transatlantic.sais-jhu.edu/partnerships/Cornerstone%20Project/cornerstone_project_morrall.pdf.

chain preventive approach and allocates primary responsibility of ensuring food safety to the private sector through obligations such as the development of preventive and recall plans.⁹⁵

Against the backdrop of a fairly sophisticated safety law, private sector has additional margin of participation to help optimize limited public resource. Two key areas are standard-setting and cross-border trade. With respect to standardsetting, future reforms could emulate China's amended Food Safety Law and encourage industry actors to adopt industry and enterprise standards that are more stringent than national standards. After all, national standards constitute a floor that accounts for feasibility across the country, and private sector actors should be prompted to elevate their own standards, which may eventually feed back into the national standards.

As to cross-border trade, currently, the supervisory and monitoring obligation primarily resides with the State.⁹⁶ The government could galvanize importers into enhanced supervision of foreign producers, akin to China's amended Food Safety Law, FSMA, and EU General Food Law. This could take the form of mandatory third-party certification under FSMA or a review system of foreign exporters and producers by importers as required under China's amended Food Safety Law.

To be clear, this article does not endorse wholesale privatization in these areas. Piecemeal reform, preferably under governmental supervision, could better calibrate for local needs, including developmental and distributive objectives. For instance, a third-party certification system for cross-border trade could begin with pilot sectors.

Third, relatedly, the three WTO Members should advocate for the adoption of these converging themes to promote food safety globally. Indeed, due to the remarkable regulatory interdependence at the global level,⁹⁷ these converging themes not only reveal a growing trend of regulation, but also exemplifies useful institutional designs with positive spillover effects on other countries.⁹⁸ More specifically, as regulatory agencies are highly interdependent in the international trading system where food products are produced, transported, reproduced, distributed, marketed, and consumed globally, regulatory initiatives and

⁹⁵ Implementing Rules and Regulations of the Food Safety Act of 2013, Sections 2, 13, 14, http://www.gov.ph/2015/02/20/implementing-rules-and-regulations-of-republic-act-no-10611.

⁹⁶ Id., Section 12.

⁹⁷ Lin (2011), *supra* note 35, at 647-49, 660-61.

⁹⁸ See Lin (2012), *supra* note 87, at 731-32.

innovations affect other parts of the world, directly or indirectly.⁹⁹ As a government undergoes structural changes and legal reforms, the improved regulatory environment benefits the country itself as well as other trading partners. For instance, when China centralizes its food safety authorities to avoid agency jurisdictional overlaps and to tighten up its outbreak response system, other countries trading with China potentially benefit from its regulatory improvement.¹⁰⁰

Notably, to accelerate the uptake of the converging practices, the three Members could devote resources to capacity building in interested countries. Indeed, capacity constraints could be particularly acute in technically and financially demanding reforms such as fashioning a more science-based regulatory architecture. To that end, existing efforts exemplified by the European Union's support of establishment of the ASEAN Risk Assessment Centre for Food Safety could be intensified.¹⁰¹

Fourth, as a final observation, these converging themes unveil the limited role of civil society. Notwithstanding the recent wave of food safety legislative updates, government and industry continue to dominate food safety governance, and civil society has generally remained peripheral. To be sure, civil society has evolved from its nascent phase to shoulder increasingly bigger responsibilities¹⁰² through its own will or governmental policy, and its growing diversity is concomitant with contemporary food related issues.¹⁰³ For instance, some local governments in China have encouraged more consumer testing by contracting with testing agencies to allow individual consumers to test their samples for free.¹⁰⁴ Additionally, as the resistance to TTIP demonstrates, some civil society groups are well-organized and vocal and are being heard by relevant regulators and standard-setting organizations.¹⁰⁵

⁹⁹ Id.

¹⁰⁰ Id.

¹⁰¹ See Overview, ASEAN Risk Assessment Centre for Food Safety, <u>http://www.arac-asean.org/about/overview.html</u>.

¹⁰² See Scott S., Z. Si, T. Schumilas, & A. Chen.. *Contradictions in state- and civil society-driven developments in China's ecological agriculture sector*, 45(2) FOOD POL'Y 158–166 (2014).

¹⁰³ See, e.g., Henk Renting & Han Wiskerke, New Emerging Roles for Public Institutions and Civil Society in the Promotion of Sustainable Local Agro-Food Systems Wiskerke, https://www.researchgate.net/profile/Henk_Renting/publication/46384072_New_Emerg ing_Roles_for_Public_Institutions_and_Civil_Society_in_the_Promotion_of_Sustainable_ Local_Agro-Food_Systems/links/09e4150fd43c8806f8000000.pdf.

¹⁰⁴ Kuhlmann et al, *supra* note 46, 19 (2017).

¹⁰⁵ See, e.g., Civil Society's Concerns about the Transatlantic Trade and Investment Partnership, DIRECTORATE-GENERAL FOR EXTERNAL POLICIES, POLICY DEPARTMENT, EUROPEAN PARLIAMENT,

Still, the depth and sophistication of civil society engagement have yet to serve as a major factor in informing and driving public policy and changing industry policy and behaviour. Food safety regimes, as seen through the biggest markets, are predominantly top-down rather than bottom-up. Governments should seek to devise ways to discern and infuse legitimate public preferences into the remit of food safety regulation.

VI. CONCLUSION

For more than two decades, the global food safety regime has been built on the tenets of and flexibilities accorded by the SPS Agreement. The resulting fragmentation of food safety governance has hampered top-down management of SPS collaboration through the multilateral mechanism.

Meanwhile, the recent tide of legislative update in the United States, the European Union, and China has given rise to several nodes of convergence. These include the paradigm shift from reaction to prevention-based system, a move away from a sectional to an integrated supply-chain approach, the centrality of science, and increasing responsibility of private actors. While the ultimate alignment of these food safety regimes is qualified by regulatory culture and market and industry structures, WTO Members could harness these bottom-up unifying features in several respects. Indeed, they constitute a foundation for future international cooperation, a blueprint for other countries to update their food safety regime, a source of positive spillover that should be replicated, and a reminder for additional civil society participation.

http://www.europarl.europa.eu/RegData/etudes/IDAN/2014/536404/EXPO_IDA(201 4)536404_EN.pdf; *Statement by 170 Civil Society Organisations on Regulatory Cooperation in EU-US Trade Talks*, CORPORATE EUROPE OBSERVATORY, https://corporateeurope.org/international-trade/2015/02/statement-170-civil-societyorganisations-regulatory-cooperation-eu-us; TIM LANG & MICHAEL HEASMAN, FOOD WARS: THE GLOBAL BATTLE FOR MOUTHS, MINDS AND MARKETS 140 (2000).