

A New Governance Recipe for Food Safety Regulation

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Although food safety is a significant and increasing global health concern, international economic law does not adequately address today's global food safety needs. While most countries rely on a collection of formalized legal rules to protect food safety, these rules too often fall short. As fiscal constraints impede raising the number of border inspections, formal international commitments (treaties) frequently limit governmental efforts to raise food safety standards. Private companies, meanwhile, can readily adopt higher standards to meet consumer demands and supply chain needs, thus demonstrating more nimbleness and flexibility in adopting the highest food safety standards available. Can countries learn from private motivations in overseeing supply chains while staying true to their formal commitments?

This Article documents a novel legal concept—the growing use of private standards to ensure food safety—reinforced by recent legislation in the United States and elsewhere. While this “New Governance” strategy allows countries to institutionalize the types of steps already taken by private actors, this model is not perfect and additional regulatory oversight and guidance will be necessary to ensure that a reformed New Governance works in this context. This Article confronts the motivations, tensions, and controversies that arise with implementing a New Governance model for food safety and provides a roadmap for achieving higher food safety goals.

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INTRODUCTION

Guaranteeing food safety is hard, if not impossible. Over fifty years ago, most farmers in the United States were small and sold goods locally. As John Fagan writes, back then, “[w]hen Grandmother went shopping, she would look the farmer or butcher in the eye and ask, ‘Is this fresh and flavorful?’ . . . In that day, there was a personal basis upon which trust was developed between buyer and seller,”¹ and the supplier knew that if he or she did not answer accurately, Grandmother would go to a different vendor next week. This kind of trust no longer exists in the food industry. Serious foodborne disease² outbreaks have

1. John Fagan, *Cert ID, A Successful Example of an Independent, Third-Party, Private Certification System 1* (Jan. 28, 2003) (unpublished manuscript), <http://www.farmfoundation.org/projects/documents/fagan.pdf>.

2. Foodborne illnesses are usually infectious or toxic in nature and caused by bacteria, viruses, parasites, or chemical substances entering the body through contaminated food or water. See *Food Safety Fact Sheet No. 399*, WORLD HEALTH ORG. (Dec. 2015), <http://www.who.int/mediacentre/factsheets/fs399/en/>.

occurred on every continent in the past decade, often exacerbated by increasing food supply chains, globalized trade,³ and distribution networks.⁴

Food contamination is a realistic, ever-present risk. If the 2008 Chinese infant formula scandal⁵ taught us anything, it is that a food scandal can have global implications. The food industry is the world's largest industry, with numerous sectors and global production chains generating trillions in annual revenues.⁶ In 2008, as officials assured the American public that no Chinese manufacturers of infant formula were registered to sell infant formula in the United States,⁷ the scandal was wreaking havoc on many economies—affecting global contracts, instilling an irreversible loss of confidence for Chinese food, and perpetuating a general skepticism for food trade. As supply chains continue to expand, concern over food safety will only intensify. One commentator notes, when “more large-scale labor markets compete for their share of international trade, the incentives to cut corners will

3. Food and Drug Administration (“FDA”) regulated imports have grown substantially. In 2009, \$2 trillion in FDA-regulated products (e.g., fresh fruits and vegetables and pantry staples including coffee, tea, and cocoa) manufactured in more than 300,000 foreign facilities entered the United States from over 150 countries. From fiscal years 2002–2010, overall U.S. food imports nearly doubled, and since 2000, imports of fresh fruits, vegetables, coffee, tea, and cocoa have more than doubled. U.S. FOOD & DRUG ADMIN., GLOBAL ENGAGEMENT 1–4 (2012), <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/ucm298578.pdf>.

4. See *Food Safety Fact Sheet*, *supra* note 2 (detailing the China Infant formula scandal—which involved infant formula contaminated with melamine and affected 300,000 infants and children, six of whom died, in China alone—and the 2011 E coli outbreak in Germany—which was linked to contaminated fenugreek sprouts (cases were reported in eight countries in Europe and North America), and caused \$1.3 billion in losses for farmers and industries and \$236 million in emergency aid payments to twenty-two EU member States, and led to fifty-three deaths); see also, World Health Org. [WHO], *Food Safety: An Essential Public Health Issue for the New Millennium*, at 9, WHO Doc. WHO/SDE/PHE/FOS/99.4 (1999), <http://apps.who.int/iris/handle/10665/65971> (noting that in developed and developing countries combined, contaminated food contributes to 1.5 billion cases of diarrhea in children each year, resulting in more than 3 million premature deaths). The U.S. Centers for Disease Control and Prevention (“CDC”), estimates that within the United States, foodborne diseases cause: approximately 48 million illnesses, 128,000 hospitalizations, and 3000 annual deaths. CTRS. FOR DISEASE CONTROL & PREVENTION, CDC ESTIMATES OF FOODBORNE ILLNESS IN THE UNITED STATES (2011), www.cdc.gov/foodborneburden/PDFs/factsheet_A_Findings_updated4-13.pdf.

5. Mark McDonald, *From Milk to Peas, a Chinese Food-Safety Mess*, N.Y. TIMES (June 21, 2012), http://rendezvous.blogs.nytimes.com/2012/06/21/from-milk-to-peas-a-chinese-food-safety-mess/?ref=topics&_r=0 (explaining that in 2008, six children died and some 300,000 fell sick from melamine, an industrial chemical used to make fertilizer and plastic pipe, found in Chinese-manufactured infant formula).

6. IMAP, FOOD AND BEVERAGE INDUSTRY GLOBAL REPORT—2010 (2010), http://www.imap.com/imap/media/resources/IMAP_Food_Beverage_Report_WEB_AD6498A02CAF4.pdf.

7. *Melamine Contamination in China*, U.S. FOOD & DRUG ADMIN. (Jan. 5, 2009), <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm179005.htm> (noting 7 trillion in annual revenue).

increase and the temptation to overlook hazardous goods might become a more common occurrence.”⁸

As countries feel pressure to raise food safety standards⁹ they are realizing that the same formal rules and practices that promise greater trade may, in fact, be limiting their regulatory options.¹⁰ Frequent “budget cuts” reduce the capacity to perform periodic inspections to assess compliance¹¹ and formal international commitments (treaties) keep countries from setting higher-than-the-default food safety standards that could be perceived as protectionist.¹² Current negotiations on the Transatlantic Trade and Investment Partnership¹³ and the Trans-Pacific Partnership,¹⁴ exemplify the range of discussion on regulatory autonomy. Some sources claim that the Transatlantic Trade and Investment Partnership is watering down EU food safety standards, while the Trans-Pacific Partnership is suppressing the right to pursue regulatory goals.¹⁵

These comments suggest that governments lack nimbleness and flexibility to easily adopt higher food safety standards. In contrast, private companies have shown their agility to adopt higher standards to meet their supply chain needs. In the last ten years, private food safety codes and supply chain contracts crossing international boundaries have proliferated, setting the stage for a transition in how food safety is regulated on a global scale.

8. Louis Klarevas, *Food: An Issue of National Security*, FORBES (Oct. 25, 2008, 12:00 AM), http://www.forbes.com/2008/10/24/food-national-security-oped-cx_lk_1025klarevas.html.

9. See generally ED RANDALL, *FOOD, RISK, AND POLITICS: SCARE, SCANDAL, AND CRISIS—INSIGHTS INTO THE RISK POLITICS OF FOOD SAFETY* (2009).

10. See generally Kenneth W. Abbott & Duncan Snidal, *Strengthening International Regulation Through Transnational New Governance: Overcoming the Orchestration Deficit*, 42 VAND. J. TRANSNAT'L L. 501 (2009); see also Ching-Fu Lin, Comment, *SPS-Plus and Bilateral Treaty Network: A “Global” Solution to the Global Food-Safety Problem?*, 29 WIS. INT'L L.J. 694 (2012).

11. See Paul Verbruggen & Tetty Havinga, *Food Safety Meta-Controls in the Netherlands 6* (Nijmegen Sociology of Law Working Paper Series, No. 2014/07, July 2014), http://www.researchgate.net/publication/270585728_Food_Safety_Meta-Controls_in_the_Netherlands.

12. See Simon Lester, *Talk of a ‘Right to Regulate’ is Hurting the Trade Debate*, HUFFINGTON POST (July 21, 2015, 8:44 AM), http://www.huffingtonpost.com/simon-lester/talk-of-a-right-to-regula_b_7839680.html.

13. The Transatlantic Trade and Investment Partnership is in negotiation between the United States and Europe.

14. The Trans-Pacific Partnership is a negotiation between the United States, Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam.

15. See Gabrielle Chan, *Trans-Pacific Partnership Could Prevent Clearer Food Labeling—Health Advocates*, GUARDIAN (Feb. 27, 2015, 5:28 PM), <http://www.theguardian.com/australia-news/2015/feb/28/trans-pacific-partnership-could-prevent-clearer-food-labelling-health-advocates>.

This Article focuses on food safety, yet the discussion speaks broadly to policymakers in other fields wrestling with the opportunities and perils of using private entities to provide traditional public services. This Article proceeds as follows, and in so doing contributes to the literatures on New Governance, Transnational New Governance, and Global Food Safety Regulation.

Part I presents a continuum of food safety choices available for country adoption. Three choices exist—”SPS-default,” ”SPS-*plus*,” and ”SPS-*plus plus*”—all referencing the food safety standards covered under the World Trade Organization (”WTO”) Agreement and within it, the Sanitary and Phytosanitary (”SPS”) Agreement. The SPS Agreement is the principal agreement under the umbrella of the WTO that regulates trade and indirectly, regulates food safety. The SPS Agreement contains rules applying to sanitary [human or animal health] or phytosanitary [plant health] measures, collectively ”SPS measures.” A quick example of an SPS measure is a national rule requiring that certain commodity imports adhere to a minimum pesticide residue limit. While standards are referenced throughout the WTO Agreement, food safety standards are prominently noted in the SPS Agreement and for this reason this study focuses on the SPS. The first standard is the ”SPS-default,” a standard in which countries adopt the standards promoted by the WTO, which are the Codex Alimentarius Food Safety Standards (”Codex standards”), promulgated by the Codex Commission, a global standard-setting organization responsible for setting thousands of standards and guidelines to protect health and ensure fair trade practices.¹⁶ Conveniently, the Codex standards run parallel with WTO norms as codified in the WTO Agreement. The SPS Agreement and country adoption of the Codex standards equates to *per se* consistency with the WTO Agreement.¹⁷

Achieving higher than the ”default” standard, or standards similar to those found in supply chain networks, is possible in two cases. Countries who are privileged with the capacity to enter into

16. *List of Standards*, FOOD & AGRIC. ORG.: CODEX ALIMENTARIUS, <http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/> (last visited Mar. 20, 2016).

17. Agreement on the Application of Sanitary and Phytosanitary Measures art. 2, Apr. 15, 1994, 1867 U.N.T.S. 493 [hereinafter SPS Agreement], http://www.wto.org/english/docs_e/legal_e/15-sps.pdf; see also *Pesticide Monitoring Program FY 2007*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm169577> (last updated July 17, 2015) (explaining that the SPS Agreement recognizes that 160 WTO member countries have the right to enact food safety measures to protect human, animal, or plant life or health, and requires that border measures (such as maximum residue limits or MRLs) be based on ”an assessment appropriate to the circumstances of the risk to human and animal health”).

international negotiations¹⁸ can secure higher food safety standards by pursuing “SPS-plus” standards. This is done through negotiating legal instruments that include more detailed or demanding provisions than the WTO or SPS Agreement, or that contain other regulatory or cooperative elements beyond the scope of the agreements.¹⁹ The practice of adopting SPS-plus standards into bilateral or regional agreements is sanctioned by the WTO.²⁰

A minority of countries—the United States, Canada, the Netherlands, and the United Kingdom—are adopting novel regulations that allow them to reach beyond those SPS-plus standards and pursue what I term “SPS-plus plus” standards. This new level of standard entails country use of third-party certification, and other private practices found in supply chains, supermarket programs, grocery standards, and voluntary codes and guidelines,²¹ to achieve higher standards. While Codex standards and SPS-plus standards are sanctioned by the WTO, the use of private standards is a controversial and currently unsettled area in WTO law.²²

18. See Gregory Shaffer, *Developing Country Use of the WTO Dispute Settlement System: Why it Matters, the Barriers Posed*, in *TRADE DISPUTES AND THE DISPUTE SETTLEMENT UNDERSTANDING OF THE WTO: AN INTERDISCIPLINARY ASSESSMENT* 167 (James C. Hartigan ed., 2009).

19. See Lin, *supra* note 10, at 714.

20. WTO members can enter into regional trade agreements whereby they grant more favorable conditions to parties to that arrangement than to other WTO members’ trade under specific conditions. See General Agreement on Tariffs and Trade art. XXIV, paras. 4–10, Apr. 15, 1994, 1867 U.N.T.S. 187 [hereinafter GATT], https://www.wto.org/english/res_e/booksp_e/analytic_index_e/gatt1994_09_e.htm; World Trade Org., *The WTO’s Rules*, https://www.wto.org/English/tratop_e/region_e/regul_e.htm (last visited Mar. 20, 2016) (discussion of the GATT Enabling Clause and Article V of the WTO General Agreement on Trade in Services (“GATS”).

21. RUTH KIRK-WILSON, REVIEW OF FOOD ASSURANCE SCHEMES FOR THE FOOD STANDARDS AGENCY (June 2002), <http://www.teagasc.ie/faol/NR/rdonlyres/CDCCE03B-3C84-4A05-8A59-D5423DACB4F5/57/UKreviewoffarmassurance.pdf> (noting that since the mid-2000s, the Food Standards Agency in the United Kingdom has promoted better food authorities and the activities undertaken by the private sector, mainly focusing on “farm assurance schemes”); see also CANADIAN FOOD INSPECTION AGENCY, INSPECTION MODERNIZATION: OPTIMIZING CONFIDENCE IN FOOD SAFETY—IMPROVED FOOD INSPECTION MODEL: PROPOSED DRAFT (2014), http://www.inspection.gc.ca/DAM/DAM-aboutcfia-sujetacia/STAGING/text-texte/acco_modernization_modeldraft_1344008567583_eng.pdf (announcing in 2014 that the Canadian Food Inspection Agency was to develop guidelines for the recognition of third-party service delivery providers).

22. The issue of private standards was first raised by St. Vincent and the Grenadines who, concerned about the negative impact on its banana exports of EureGAP standards for pesticides, raised a “specific trade concern” in the WTO on this issue, followed by a SPS Committee report in 2007. Note by the Secretariat, *Private Standards and the SPS Agreement*, WTO Doc. G/SPS/GEN/746 (Jan. 24, 2007) [hereinafter *Private Standards*]; see Submission by the World Organization for Animal Health, *Considerations Relevant to Private Standards in the Field of Animal Health, Food Safety, and Animal Welfare*, WTO Doc. G/SPS/GEN/822 (Feb. 25, 2008);

Part II argues that the evolving structure of global food production with multinational enterprises, supply chains,²³ and different available standards, necessitates an evolution from traditional regulation to something else.²⁴ Given current constraints on governments—financial constraints do not allow the U.S. government to increase border inspection capacity to conduct greater border inspections, and regulatory constraints that do not allow establishing protectionist trade measures—the best way to achieve higher food safety standards, SPS-plus *plus*, is to adopt private sector practices such as third-party certification, public-private partnerships, and voluntary standards. This transition from overseeing all food safety functions to “co-regulating” might be labeled, at least by some, as a form of New Governance.

Generally perceived as opposite to “command-and-control” regulation, New Governance is marked by increased collaboration of stakeholders and non-state actors, decentralization and devolution, flexibility and context specificity, and adaptability and dynamic learning.²⁵ The phenomenon of New Governance refers to a regulatory paradigm defined by privatization, decentralization, public participation, horizontal coordination, experimentation, and a solution-oriented focus.²⁶ And while there are numerous costs and benefits to using New Governance—particularly third-party certification features—anecdotal evidence indicates that the use of third-party certification leads to greater food safety transparency, cooperation and fewer food safety recalls.²⁷ While these are clearly benefits, one of the most challenging issues, highlighted by the 2011 Colorado Listeria outbreak is the credibility of food safety audits and third-party certifications.²⁸ Lytton

see also STDF Information Session on Private Standards, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/sps_e/private_standards_june08_e/private_standards_june08_e.htm (last visited Mar. 20, 2016); *Food Safety Body Agrees to E-Working Group “Time Out” on Definition of Private Standards*, WORLD TRADE ORG. (Mar. 26, 2015), https://www.wto.org/english/news_e/news15_e/sps_26mar15_e.htm.

23. See John Gerard Ruggie, *Business and Human Rights: The Evolving International Agenda*, 101 AM. J. INT’L L. 819, 823 (2007) (“[S]eventy-seven thousand transnational firms span the global economy today, with some 770,000 subsidiaries and millions of suppliers—Wal-Mart alone is reported to have more than sixty thousand suppliers.”).

24. See Abbott & Snidal, *supra* note 10, at 505.

25. See Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342 (2004).

26. See *id.*; see also Amy J. Cohen, *Negotiation, Meet New Governance: Interests, Skills, and Selves*, 33 LAW & SOC. INQUIRY 503 (2008) (discussing the experimentation thread of New Governance).

27. See Timothy D. Lytton & Lesley K. McAllister, *Oversight in Private Food Safety Auditing: Addressing Auditor Conflict of Interest*, 2014 WIS. L. REV. 289, 289–94 (discussing the role of private actors in food safety governance).

28. In the 2011 Listeria outbreak implicating cantaloupes, a wrongful death claim was brought

and McAllister note the structural conflict of interest that exists when private auditors are paid for by the auditees—a conflict between the financial interest of the auditor and protecting the public from food safety risks. The 2011 Colorado Listeria outbreak underscores the potential weakness of the New Governance framework.

Despite its shortcomings, Part III endorses New Governance as a good framework for food safety. Recent U.S. food safety legislation, the Food Safety Modernization Act of 2011 (“FSMA”)²⁹—passed in response to growing levels of imports, diminishing resources to inspect, and heightened food safety risks³⁰—adopts key New Governance features: third-party certification voluntary standards³¹ and public-private partnerships.³² The new rules are introduced both (1) as a role model for emerging food safety practice, and (2) to show policymakers that once they can see the regulatory regime within the New Governance framework, certain lessons are clarified and are readily available for implementation. In some cases, I show that more legislative authority or guidance is necessary: for example, with respect to conflicts of interest, third-party auditors are not prevented from working in-house for their clients, and auditors are not prevented from performing other services for their auditees; the “checklist mentality” should be addressed by requiring a certain number of unannounced visits, as is being considered by the Global Food Safety Initiative (“GFSI”); and auditors should be required to complete certain defined

against the retailer, Wal-Mart who in turn, filed a complaint in 2014 in a Wyoming court asserting third-party claims against the grower (Jensen Farms), the distributor (Frontera Produce Ltd.) and the third-party auditors (Primus Group Inc. and Bio Food Safety Inc.). Primus subcontracted Bio Food Safety to undertake the on-site audit of the cantaloupe farm, which resulted in a nearly perfect rating. While this case involved an unsuccessful audit to a domestic producer, it revealed possible “blind spots” in the privatization of third-party certification. Tom Karst, *Wal-Mart Files Suit in Jensen Cantaloupe Case*, PRODUCE RETAILER (Feb. 14, 2014, 5:10 PM), <http://www.produceretailer.com/produce-retailer-news/Wal-Mart-files-suit-in-Jensen-cantaloupe-case-245591681.html>.

29. See FDA Food Safety Modernization Act (FSMA), Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 21 U.S.C.) (amending the Federal Food, Drug, and Cosmetic Act (codified as amended at 21 U.S.C. § 301–399f)). Third-party certification means that an independent organization has reviewed the manufacturing process of a product and has independently determined that the final product complies with specific standards for safety, quality, or performance. Certified products bear the certifier’s mark on their package.

30. See Alexia Brunet Marks, *The Risks We Are Willing to Eat: Food Imports and Safety*, 52 HARV. J. ON LEGIS. 125 (2015).

31. See 21 U.S.C. § 384b (2012) (explaining that for importers who want to voluntarily participate in the program, the Voluntary Qualified Importer Program provides for the expedited review and importation of food offered for importation).

32. See *id.* § 381. For a description of several voluntary system recognition agreements, see *FDA Recognizes New Zealand as Having a Comparable Food Safety System*, FDA (Dec. 13, 2012), <http://www.fda.gov/food/newsevents/constituentupdates/ucm331276.htm>.

coursework and field training instead of fulfilling recommendations. In other respects, more legislative authority is not necessary—arguably, the FSMA rules are appropriate with respect to the requirement to disclose, and managing third-party certifiers. In essence, part of my contribution is using the New Governance model and literature to diagnose New Governance failures (e.g., 2011 Colorado Listeria) and provide correctives going forward.

I. A SMORGASBORD OF FOOD SAFETY STANDARDS

The multitude of food safety standards can be organized along a continuum from default to higher standards. This Part describes this continuum in ways that illustrate both the barriers that governments face in developing higher standards as well as the comparative flexibility enjoyed by private actors.

It is useful to distinguish between two major groups of Codex Alimentarius Commission standards relating to food safety, numerical standards and process standards.³³ *Numerical standards* are food safety limits that include maximum residue limits (“MRLs”) on pesticide residue and veterinary drug residue³⁴ and maximum levels for contaminants³⁵ and food additives.³⁶ Codex also sets limits, or

33. See Marks, *supra* note 30, at 152.

34. According to the Codex Alimentarius Commission, MRLs are listed for pesticide and veterinary drug residues. See CODEX ALIMENTARIUS COMM’N, PROCEDURES MANUAL 24–26 (24th ed. 2015). Pesticides residues include: insecticides, acaricides, rodenticides, fungicides, herbicides, and plant growth regulators, among others. *Pesticide Residues in Food and Feed*, FOOD & AGRIC. ORG.: CODEX ALIMENTARIUS, <http://www.fao.org/fao-who-codexalimentarius/standards/pestres/functional-classes/en/> (last visited Mar. 20, 2016). Veterinary drug are defined by the Commission as “substance[s] applied or administered to any food producing animal . . . whether for therapeutic, prophylactic, or diagnostic purposes or for modification of physiological functions or behaviour.” CODEX ALIMENTARIUS COMM’N, *supra*, at 25.

35. From the Codex Procedural Manual, a contaminant is

any substance not intentionally added to food or feed for food producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination.

Id. at 24 (emphasis omitted). In addition, Codex bans substances such as melamine. See Press Release, World Health Org., International Experts Limit Melamine Levels in Food (July 6, 2010), http://www.who.int/mediacentre/news/releases/2010/melamine_food_20100706/en/.

36. Codex limits the definition of food additives to substances intentionally added to food for a technological purpose, and uses a “maximum use level” to determine the “highest concentration of the additive determined to be functionally effective in food or food category and agreed to be safe by the Codex Alimentarius Commission.” World Health Org. [WHO], *General Standard for Food Additives*, at 2–3, Codex Stan 192 (rev. 2015), <http://www.fao.org/fao-who-codexalimentarius/standards/gsfa/en/>. The Codex General Standard on Food Additives does not include food ingredients, processing aids, contaminants, pesticides, vet drugs, and nutrients.

microbiological criteria, for pathogenic microorganisms.³⁷ For example, consider that you want to import apples from Chile. U.S. Customs officials regulate fruit imports under the Food, Drug and Cosmetics Act of 1938, amended by the FSMA.³⁸ Among other requirements, these rules specify U.S. Environmental Protection Agency acceptable MRLs.³⁹ The United States regulates 126 pesticides for U.S.-destined apples, with specific levels for each pesticide in question.⁴⁰ These are *numerical standards*.

An example of *process standards* is the Codex Code of Hygienic Practices, which stipulates elements of good practice in the management of all operations along the food chain and in procedures for establishing compliance with these operations. For instance, foreign apple imports must meet U.S. agricultural production requirements calling for risk-based preventative controls.⁴¹ The agricultural production requirements are *process standards*. This Article presents higher standards that are both numerical and process in nature.

Beyond establishing rules to ensure the safety of food imports, much more goes into instilling a culture of food safety. One example of how a low rate of inspection instills little incentive for compliance and can erode a regulation and create significant food safety risk is particularly revealing. A 2012 study estimating the amount of excess pesticide residue levels for the top twenty imported produce items (based on quantities imported and U.S. consumption levels) found that if the United States allowed the levels of those of the originating countries, nearly twenty thousand kilograms of pesticides in excess of U.S. tolerances could potentially be imported to the United States—in cases

37. Under its working definition, Codex has explained a microbiological criterion as “defin[ing] the acceptability of a product or a food lot based on the absence or presence, or number of microorganisms including parasites and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area, or lot.” Food & Agric. Org. [FAO], *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods*, FAO Doc. CAC/GL 21 (1997), www.fao.org/input/download/standards/394/CXG_021e.pdf.

38. See FSMA, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 21 U.S.C.).

39. *Navigating the Continuing Challenge of Pesticide MRLs*, DFA CAL. (July 2015), <http://www.dfaofca.com/issue-34-july-2015/navigating-the-continuing-challenge-of-pesticide-mrls/> (noting the U.S. Environmental Protection Agency’s (“EPA”) work with Codex to harmonize MRLs, from the perspective of a food sector company).

40. The EPA establishes the list of pesticide residue limits for commodities. 40 C.F.R. § 180.1–6 (2015) (U.S. pesticide tolerances); 21 C.F.R. § 556.1 (2015) (U.S. veterinary drug tolerances); see also GLOBAL MRL DATABASE, <https://www.globalmrl.com/> (last visited Mar. 20, 2016) (providing, via subscription service, global MRLs in force for raw and processed commodities, among other MRL-related information).

41. See 21 U.S.C. § 350g (2012).

where U.S. regulations are more protective than those of originating countries.⁴² Without proper enforcement and compliance, national rules cannot prevent food safety risks from entering national borders.

Table 1 loosely depicts a continuum of food safety standards. From top to bottom, the table shows minimum food safety standards moving toward higher food safety standards. According to the table, “SPS-default” or minimum standards are provided by public international treaties such as the WTO and Codex, while higher standards are available through bilateral and regional trade agreements and private standards. The FSMA, which amends the Food Drug and Cosmetics Act of 1938, supports higher food standards, SPS-*plus* and SPS-*plus plus*, through the use of system recognition (bilateral) agreements (see *infra* Part I.B) and private certification.

Table 1: Global Food Safety Standards Architecture

Food Safety Standard	Practices, Policies and Formal Commitments that Support the Standard
1. SPS-default	Multilateral Agreements: WTO and CODEX
2. SPS- <i>plus</i>	Bilateral Agreements and Regional Trade Agreements
3. SPS- <i>plus plus</i>	Private Standards

A. The Default Standard

The default food safety standard, “SPS-default,” is a set of standards established by the Codex Alimentarius Commission and adopted by the WTO. Because most countries are WTO members, most countries ascribe to the default rules.

1. The Codex Alimentarius

Minimum, baseline standards are those set by the Codex Alimentarius Commission and are supported and enforced, in part, by the WTO. Codex was formed in 1963 by the Food and Agriculture Organization and the World Health Organization of the United Nations to develop food standards, guidelines, and related texts such as codes of practice. Under the SPS Agreement, Codex is recognized as the

42. Roni A. Neff et al., *A Comparative Study of Allowable Pesticide Residue Levels on Produce in the United States*, GLOBALIZATION & HEALTH, 2012, at 8:2, <http://www.globalizationandhealth.com/content/8/1/2>.

international standards organization for food safety. If the United States adopts registration and other standards based on Codex recommendations, the adopted standards will be per se consistent with the SPS Agreement and of the General Agreement on Tariffs and Trade (“GATT”).⁴³ WTO members that wish to apply stricter food safety measures than those set by Codex are required to justify these measures scientifically. While Codex recommendations are purely voluntary, Codex has a far reaching impact in that its 159 members cover 99% of the world’s population, it promulgates 336 standards and guidelines, and many of these standards are used to resolve trade disputes and to draft national legislation.⁴⁴

Most countries adopt Codex standards. Continuing with the earlier example on apples, Codex sets maximum residue limits, or MRLs, for pesticide residue levels. National governments often choose to benchmark their MRL to Codex but sometimes set their own MRLs or use another country’s MRLs.⁴⁵ The European Union maintains its own set of MRL standards, which became harmonized across member states in 2008, while Mexico defaults to U.S. MRLs.⁴⁶ Other countries, including Japan, Canada, Brazil, and Argentina, maintain their own standards. Unless a bilateral treaty is in place with the exporting country, higher standards can only be adopted while considering WTO obligations.⁴⁷ The exception is supply chains, where higher standards may also exist. While collective private food standards such as GlobalGAP refer to prevailing Codex MRLs, they *do not* set additional requirements; private retailers do, however, set stricter standards.⁴⁸

43. See SPS Agreement, *supra* note 17, at art. 3.2.

44. See *About Codex*, FOOD & AGRIC. ORG.: CODEX ALIMENTARIUS, <http://www.fao.org/fao-who-codexalimentarius/about-codex/en/> (last visited Mar. 20, 2016).

45. See *Maximum Residue Limits (MRL) Database*, U.S. DEP’T OF AGRIC.: FOREIGN AGRIC. SERV., <http://www.fas.usda.gov/maximum-residue-limits-mrl-database> (last visited Mar. 20, 2016) (online database containing seventy country MRLs).

46. *Plants: EU Legislation on MRLs*, EUR. COMMISSION, http://ec.europa.eu/food/plant/pesticides/max_residue_levels/eu_rules/index_en.htm (last updated Feb. 17, 2016); see also U.S. DEP’T AGRIC., MX5049, MEXICO’S MAXIMUM RESIDUE LIMIT (MRL) POLICY (2005), <http://apps.fas.usda.gov/gainfiles/200505/146129840.pdf>.

47. The European Communities-Hormones dispute is an example of a higher standard being applied. In the WTO dispute, the United States claimed that the hormone level ban imposed by the European Union ran counter to Codex MRL standards. The European Union argued that MRL standards did not apply to the hormone in question. Therefore, the Appellate Body of the WTO did not decide on MRL standards specifically, but it was raised in discussion. Next, in the 1990s the European Union announced to the WTO a heightened national standard with regards to aflatoxin. After concern from developing countries, the European Union decided to revise the standard ultimately settling on the Codex standards. See U.S. DEP’T OF AGRIC., WRS-98-4, AGRICULTURE IN THE WTO (1998), <http://www.ers.usda.gov/media/1774123/wrs98-4.pdf>.

48. Renata Clarke, Food & Agric. Org., Private Food Safety Standards: Their Role in Food

Retailers may prefer higher food safety standards for reputation, as a comparative advantage, or to reduce liability, among other reasons. Some retailers impose limits that are more stringent than national limits, sometimes ranging from 25%–80% of the national MRL.⁴⁹ Despite being a fraction of the national limits, these retailer percentages are more stringent because farmers would rather apply more, *not less*, pesticides to eradicate pest diseases.

2. The WTO Agreement

Although primarily a trade-promoting organization, the WTO also promotes international standards and monitors national food safety rules to prevent protectionism and discrimination.⁵⁰ The WTO Sanitary and Phytosanitary Agreement (“SPS Agreement”) refers to Codex standards as the benchmark for food safety in international trade, and calls for harmonization of national standards with Codex as an important strategy for facilitating trade.⁵¹

The SPS Agreement was negotiated during the Uruguay Round of trade negotiations in 1995, when over 100 national governments signed the WTO agreement to prevent members from enacting food safety measures that act as unfair barriers to trade.⁵² The SPS Agreement recognizes that WTO member countries have the right to enact food safety regulations called “sanitary [human or animal health] or phytosanitary [plant health] measures” to the “extent necessary to protect human, animal or plant life or health.”⁵³ Notably, measures are adopted by a government that directly or indirectly affect international trade, and measures are applied to protect human, animal, or plant life and health from a series of different risks arising from animals or plants or from contaminants, toxins, and additives in food. As noted earlier with the apple example, a requirement to inspect for pesticide residues at the border is an example of an SPS measure.

A member country needs to determine the appropriate level of protection that it wants to achieve (e.g., the standards it wants to follow); from there, each measure must follow a set of basic obligations.

Safety Regulation and Their Impact 11 (2010), <http://www.fao.org/docrep/016/ap236e/ap236e.pdf> (presenting standards for twelve private retailers).

49. *Id.*

50. See WTO, <http://www.wto.org> (last visited Mar. 20, 2016).

51. See SPS Agreement, *supra* note 17.

52. See SPS Agreement, *supra* note 17. For an interesting discussion on how to reconcile the pro-health and pro-trade distinctions within the SPS agreement, see Lin, *supra* note 10, at 714 n.132.

53. SPS Agreement, *supra* note 17, at art. 2.2.

Overall, measures must not “arbitrarily or unjustifiably discriminate” against other member countries and must not operate as a “disguised restriction on international trade.”⁵⁴ Further, SPS measures must be applied consistently across comparable situations to avoid “arbitrary or unjustifiable” levels of protection that result in “discrimination or a disguised restriction on international trade.”⁵⁵

Members are encouraged to harmonize SPS measures “on as wide a basis as possible” by utilizing “international standards” put forward by either Codex, the World Organization for Animal Health, the International Plant Protection Convention, or based on a member’s own risk assessment.⁵⁶ An SPS measure that conforms to international standards enjoys a presumption of validity.⁵⁷ Members are also encouraged to harmonize with each other’s standards by accepting as equivalent the SPS measures of other members, “even if these measures differ from their own or from those used by other [m]embers trading in the same product, if the exporting [m]ember objectively demonstrates to the importing [m]ember that its measures achieve the importing [m]ember’s appropriate level of sanitary or phytosanitary protection.”⁵⁸

If a member wishes to adopt an SPS measure establishing a higher level of protection than the international standard, it must demonstrate that the SPS measure is “based on” scientific evidence and bears a “rational relationship” between the SPS measure and the risk assessment itself.⁵⁹ The risk-assessment process ensures that “control, inspection and approval procedures” do not limit arbitrarily or unjustifiably the importation of food.⁶⁰ Finally, members should also consider the impact of measures on other countries by considering the technical and economic feasibility for the importing member, as well as alternative or equivalent approaches to limiting risk.⁶¹

Members can bring WTO disputes against nonconforming measures and the WTO can require members who violate the SPS Agreement to modify or withdraw their noncompliant measures. While the WTO cannot *force* a member government to change its measures, it has the

54. *Id.* at art. 2.3.

55. *Id.* at art. 5.5.

56. *Id.* at art. 3.1, Annex A-5.

57. *Id.* at arts. 2.4, 3.2.

58. *Id.* at art. 4.1.

59. *Id.* at art. 3.3; Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, ¶ 193, WTO Docs. WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998).

60. SPS Agreement, *supra* note 17, at art. 8.

61. *Id.* at arts. 2, 5, 6.

power to authorize those countries adversely affected to retaliate.⁶² Still, WTO critics argue that, under the SPS Agreement, the “WTO may force a nation to choose between weakening its high standards . . . or paying an international penalty,”⁶³ and “pressure for downward harmonization is built directly into the SPS Agreement because it is designed to facilitate trade, not to raise health and safety standards.”⁶⁴ This is unsurprising as members in a multilateral treaty usually concede to compromises around the lowest common denominator.⁶⁵

B. Higher “Top Shelf” Standards

Higher standards exist under two circumstances. First, “SPS-plus” standards exist when countries draft a bilateral treaty or memorandum of understanding (“MOU”) to address specific food safety risks with specific countries. Second, what I term “SPS-plus plus” standards exist via private standards, which have proliferated due to demand-driven supply-chain preferences.

1. Bilateral Treaties, SPS Chapters, and Memoranda of Understanding

Governments use a variety of different approaches to address emerging food safety needs and their potential for enhancing food safety, such as: signing a bilateral treaty,⁶⁶ incorporating an SPS chapter

62. MICHAEL J. TREBILCOCK & ROBERT HOWSE, *THE REGULATION OF INTERNATIONAL TRADE* 37 (2d ed. 1999). If the aggrieved party wins, the WTO permits the aggrieved member to suspend previously granted trade concessions to the violating country, typically by raising tariff rates on the country’s exports.

63. See Bruce Silverglade, *The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulations to Facilitate Trade?*, 55 *FOOD & DRUG L.J.* 517, 517 (2000); see also Lydia Zuraw, *Critics Say Food Safety Standards Could be Threatened by U.S./EU Trade Agreement*, *FOOD SAFETY NEWS* (May 16, 2014), <http://www.foodsafetynews.com/2014/05/food-safety-standards-could-be-threatened-in-u-s-eu-trade-agreement/#.U-gLQmPou8w> (noting that in the Transatlantic Trade and Investment Partnership, the United States and European Union are bargaining for strong positions with respect to agriculture). The European Union fears compromising on a ban on genetically engineered crops, meat from livestock treated with non-therapeutic antibiotics and growth hormones, ractopamine, and chemically washed poultry, plus standards for things such as animal welfare, organic equivalency, chemicals, and nanotechnology. Meanwhile, the United States fears compromising on standards for feed ingredients that include ruminant materials known to transmit mad cow disease; the zero-tolerance policy for *Listeria* and *E. coli* could be eliminated; genetically engineered labeling initiatives across the United States could be threatened if the European Union lowers its labeling requirements; “Buy American” policies could be eliminated; and Europe’s milk standards could be deemed equivalent to those of the United States.

64. Silverglade, *supra* note 63, at 520.

65. See Lin, *supra* note 10, at 729.

66. An example is the U.S.-China Food Safety Agreement. See Agreement Between the United States of America and the General Administration of Quality Supervision, Inspection and Quarantine of the People’s Republic of China on Food and Feed, U.S.-China, Dec. 11, 2007, <http://www.state.gov/documents/organization/108850.pdf> [hereinafter U.S.-China Agreement].

(food safety related) into a free trade agreement,⁶⁷ and signing an MOU⁶⁸ or other cooperative agreement,⁶⁹ confidentiality agreement,⁷⁰ or system recognition agreement (bilateral agreements signed by countries with compatible food safety systems).⁷¹ All of these methods are housed under the bilateral agreement umbrella.

Bilateral agreements are gaining popularity. As of 2011, the United States has 110 international arrangements (104 are bilateral), at least fifty-six of which are directly related to food safety or SPS issues.⁷² The 110 agreements include sixty-seven MOUs and other cooperative arrangements, and thirty-four confidentiality commitments under the Food and Drug Administration International Programs.⁷³ These agreements could serve as models for bilateral agreements between trade partners to ensure the safety of food imports to the United States.⁷⁴ Countries sign bilateral agreements in an effort to reduce the cost of compliance in the long term and focus resources on a particular risk-identified issue, commodity, or country. Bilateral food safety agreements have been signed by the United States and China, and between the United States, the European Union, and Japan as pragmatic

67. SPS chapters do not impose new or additional substantive rules or obligations but do provide a forum for the resolution of these disputes and expand the scope of SPS coverage. In 2009, Japan signed bilateral free trade agreements with Switzerland and Vietnam, which include an SPS chapter. See WTO Trade Policy Review Body, *Trade Policy Review Report by Japan*, WTO Doc. WT/TPR/G/243 (Jan. 11, 2011). Leaked drafts of the Trans-Pacific Partnership Trade Globalization Agreement show that food safety is part of not one, but several conversations—sanitary and phytosanitary measures, regulatory convergence, and supply chain management. See Sharon Friel et al., *A New Generation of Trade Policy: Potential Risks to Diet-Related Health from the Trans Pacific Partnership Agreement*, GLOBALIZATION & HEALTH, 2013, at 9:46, <http://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-9-46>.

68. See *Bilateral Cooperation*, EURO. COMMISSION, http://ec.europa.eu/consumers/consumers_safety/international_cooperation/bilateral_cooperation/index_en.htm (last updated Feb. 10, 2016) (discussing the Memorandum of Understanding between the European Union and China, which occurred on January 16, 2008).

69. *International Arrangements*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/InternationalPrograms/Agreements/> (last updated Nov. 24, 2015).

70. *Id.*

71. Some of these arrangements facilitate relationships and affirm participants' commitment to strengthening existing scientific and public health protection activities related to food safety. Many are simply technical and address a narrowly defined problem or risk in a commodity exported from a specific country.

72. *International Arrangements*, *supra* note 69; see also Lin, *supra* note 10, at 704.

73. Lin, *supra* note 10, at 704.

74. See MICHAEL T. ROBERTS, NAT'L AGRIC. L. CTR., INTRODUCTION TO FOOD LAW IN THE PEOPLE'S REPUBLIC OF CHINA 13 (Nov. 2007) <http://nationalaglawcenter.org/publication/view/roberts-introduction-to-food-law-in-the-peoples-republic-of-china-national-aglaw-center-publications-11-2007/>. The United States and China concluded a bilateral agreement concerning food safety that arose as a consequence of well-publicized problems with China food imports into the United States. See U.S.-China Agreement, *supra* note 66.

approaches for imminent needs.⁷⁵

SPS-plus elements—rights and obligations that go beyond the “SPS-default”—have emerged as a common feature of bilateral agreements.⁷⁶

According to Lin, SPS-plus refers to

legal instruments that are signed by countries and that include more detailed or demanding provisions than the multilateral rules under the SPS Agreement, or that contain other regulatory or cooperative elements beyond the scope of the SPS Agreement: (1) a shift from response-oriented border inspection to a more prevention-based mechanism; (2) deeper cooperation in a more institutionalized apparatus; and (3) expansion in breadth and depth of information-sharing obligations.⁷⁷

Two interesting features distinguish SPS-default protection from SPS-plus protection. First, in contrast to the SPS Agreement’s default setting, when importing countries are responsible for implementing food safety border measures, regulations, and standards to protect citizens, exporting countries in bilateral food safety agreements absorb more of the responsibility and cost of ensuring food safety.⁷⁸ Second, Lin notes that with SPS-plus, states are institutionalizing their bilateral cooperation. For example, the EU-China Product Safety MOU asks the two sides to establish a “Joint Committee on Food Safety/SPS” and “Technical Working Group” to hold annual discussions on treaty implementation.⁷⁹ These institutional developments are not part of the SPS-default architecture, and extend the state further into advanced collaboration and cooperation in food safety governance.⁸⁰

Aside from the heightened food safety protection, there are other benefits to signing bilateral agreements. Bilateral agreements are beneficial for their information-forcing role, their ability to target

75. Lin, *supra* note 10; *see also* OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2014 REPORT ON SANITARY AND PHYTOSANITARY MEASURES 10 n.2, <http://www.ustr.gov/sites/default/files/FINAL-2014-SPS-Report-Compiled.pdf> (noting that among the U.S. free trade agreements (“FTA”) and trade promotion agreements (“TPA”) that include an SPS chapter are: the U.S.-Australia FTA, the U.S.-Bahrain FTA, the U.S.-Chile FTA, the U.S.-Columbia TPA, the Dominican Republic-Central America-U.S. FTA (“CAFTA-DR”), the U.S.-Korea FTA, the U.S.-Oman FTA, the U.S.-Panama TPA, and the U.S.-Peru TPA). The U.S.-Morocco FTA does not have a stand-alone SPS chapter, but does include various SPS provisions in its agriculture chapter.

76. *See* Lin, *supra* note 10, at 699.

77. *Id.* at 714–15 (emphasis omitted).

78. *Id.* at 716 (noting that the U.S.-China, EU-China, and Japan-China agreements express an intention to shift the burden on the exporting country by requiring registration, voluntary export bans, certificates, or on-site inspection).

79. *Id.*

80. *Id.* at 717.

specific food safety risks, and their flexibility. Also, given the compliance rate of the exporting country's products, individual agreements allow for addressing specific country and commodity risks. Finally, individual agreements can be flexible enough to provide developing countries with a feasible starting point. It has been found that the impact on national regulation will vary considerably, causing regulatory regimes to remain heterogeneous despite some harmonization.⁸¹ The Food and Agricultural Organization and the World Health Organization also recognize that food safety systems will differ and not every producer will have Hazard Analysis Critical Control Point certification.⁸² Given the heterogeneity of country capabilities, no solution will be one-size-fits-all answer. In the end, bilateral agreements represent an approach to harmonize food safety one agreement at a time. Importantly, for countries with similar levels of food safety standards, a mutual recognition or equivalence agreement will suffice; however, for countries with vastly differing levels of food safety standards, substantial tradeoffs need to be reached that could threaten heightened standards.

There is evidence that signing bilateral agreements may not achieve higher food safety levels because they place downward pressure on food safety standards. Using the Australia-U.S. free trade agreement as an example, before the trade talks ended, the United States deliberately sought changes to several critical provisions in Australia's domestic food safety legislation perceived by it as limiting U.S. export capacity—such as the use of quarantine to exclude imports that Australians considered safe.⁸³ This “race to the bottom” criticism has implications for the numerous bilateral and regional trade agreements the United States has in place, and many on the horizon,⁸⁴ including the Transatlantic Trade and Investment Partnership and the Trans-Pacific

81. Torben M. Andersen, Niels Haldrup & Jan Rose Sorensen, *Labour Market Implications of EU Product Market Integration*, 15 *ECON. POL'Y* 107 (2000).

82. Food & Agric. Org. [FAO], *FAO/WHO Guidance to Governments on the Application of HACCP in Small and/or Less-Developed Food Businesses* (2006), http://www.who.int/foodsafety/publications/fs_management/HACCP_SLDB.pdf.

83. Hilary Bambrick, *Trading in Food Safety?: The Impact of Trade Agreements on Quarantine in Australia 1* (Austl. Inst., Discussion Paper No. 73, 2004), http://www.tai.org.au/documents/dp_fulltext/DP73.pdf.

84. The United States has regional trade agreements with Canada and Mexico (NAFTA), Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua (CAFTA), and bilateral relationships with Jordan, Chile, and Singapore. It is currently negotiating with the Southern African Customs Union (includes Botswana, Lesotho, Namibia, South Africa, and Swaziland), Bahrain and Morocco. Further negotiations are planned with Thailand, Panama, Columbia, Peru, Bolivia, and Ecuador.

Partnership.⁸⁵

As noted earlier, the Transatlantic Trade and Investment Partnership and the Trans-Pacific Partnership are examples of how international commitments have the potential to constrain regulatory authority over food safety. In recent news, the Transatlantic Trade and Investment Partnership was found to erode EU food safety standards,⁸⁶ and the Transatlantic Trade and Investment Partnership has met similar criticism.⁸⁷ In the Trans-Pacific Partnership, the criticism lies in the investor-state dispute settlement mechanism pertaining to each agreement. For instance, Australian citizens raised a specific concern after the Australian government had been trying to pass a labeling law requiring the display of the country of origin on the front of packaging after a foodborne illness outbreak from imported frozen berries.⁸⁸ The concern is that under the Trans-Pacific Partnership, if a foreign company was forced to clearly label where a product was sourced and manufactured, and its sales dropped after the labeling was introduced, that company may be able to claim a loss of revenue as a result of Australian products being given an “unfair advantage.”⁸⁹ A similar clause in a Hong Kong treaty allowed Philip Morris International to take legal action against Australia over the plain packaging tobacco laws in 2011.⁹⁰ These two cases illustrate the complicated nature of international commitments and the way in which they can potentially constrain regulatory power in the food safety arena.⁹¹

Other indicators suggest that unilateral regulatory changes—usually pursued under the traditional, command-and-control paradigm—to

85. See *supra* note 13 (the Transatlantic Trade and Investment Partnership); *supra* note 14 (the Trans-Pacific Partnership).

86. See Arthur Neslen, *EU Dropped Pesticide Laws Due to US Pressure Over TTIP, Documents Reveal*, *GUARDIAN* (May 22, 2015, 6:58 AM), <http://www.theguardian.com/environment/2015/may/22/eu-dropped-pesticide-laws-due-to-us-pressure-over-ttip-documents-reveal> (noting that in negotiations, U.S. negotiators allegedly pushed the European Union to shelve action on endocrine-disrupting chemicals linked to cancer and male infertility to facilitate Transatlantic Trade and Investment Protection free trade deal).

87. See Chan, *supra* note 15.

88. Terrie Morgan, *Australian Food Labelling Laws: Changes and Complexities for Foreign Trade*, *BILATERALS.ORG* (Aug. 25, 2015), <http://www.bilaterals.org/?australian-food-labelling-laws>.

89. *Id.* The language of preventing advantages can be found in the Trans-Pacific Partnership Investment Chapter, article 9.10(2). U.S. Trade Rep., *Chapter 9: Investment*, *TRANS-PAC. P'SHIP* (Nov. 5, 2015), <https://medium.com/the-trans-pacific-partnership/investment-c76dbd892f3a>.

90. See Jerry Votava, *Philip Morris Sues to Block New Australia Tobacco Label Requirements*, *JURIST* (Nov. 21, 2011, 1:12 PM), <http://jurist.org/paperchase/2011/11/philip-morris-sues-to-block-new-australia-tobacco-label-requirements.php>.

91. See generally Alexia Brunet Marks, *The Right to Regulate (Cooperatively)*, 38 *U. PA. J. INT'L L.* (forthcoming 2016).

increase food safety may not be welcome: (1) higher national standards have recently been struck down by the WTO as protectionist suggesting a continued emphasis on scientific evidence and risk assessment to justify measures,⁹² (2) import restrictions based on foreign production processes have been struck down by the WTO as protectionist,⁹³ and (3) developed countries are being called more frequently to defend their regulatory policies before arbitral tribunals in what Wagner calls an “investor-friendly” jurisprudence.⁹⁴ This all shows that while some moves toward increasing food safety standards may be struck down by international tribunals as protectionist (e.g., WTO), others may be struck down as violating more arbitrary standards such as “fair and equitable treatment” (e.g., international investment standards).

2. Private Standards, Schemes, and Contracting

Food retailers are uniquely positioned to take advantage of higher standards—which include stricter numerical and process standards, as well as product specifications, product analysis, purchasing procedures, internal audit, and full product or ingredient traceability—the private sector, out of reach of WTO and other economic law constraints.

Generally speaking, in the food safety arena, private governance features developed through a series of events that include direct and indirect regulation.⁹⁵ Private “schemes,” which include a set of standards plus a governance structure for certification and enforcement with these features—accreditation, certification, standard setting, adoption, implementation, conformity assessment, and enforcement⁹⁶—

92. See *Japan—Measures Affecting the Importation of Apples*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds245_e.htm (last visited Mar. 20, 2016); *India—Measures Concerning the Importation of Certain Agricultural Products*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds430_e.htm (last visited Mar. 20, 2016); see also OFFICE OF THE U.S. TRADE REPRESENTATIVE, *supra* note 75.

93. See Report of the Panel, *United States—Restrictions on Imports of Tuna*, DS29/R (June 16, 1994). Yet, it bears mentioning that recent decisions show that there is hope for state regulatory space. See Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc. WT/DS58/AB/R (Oct. 12, 1998); see also JASON POTTS, INT’L INST. FOR SUSTAINABLE DEV., *THE LEGALITY OF PPMS UNDER THE GATT: CHALLENGES AND OPPORTUNITIES FOR SUSTAINABLE TRADE POLICY*, (2008), http://www.iisd.org/pdf/2008/ppms_gatt.pdf (summarizing current WTO law suggesting the expanded scope for “process and production method” regulation).

94. See Markus Wagner, *Regulatory Space in International Trade Law and International Investment Law*, 36 U. PA. J. INT’L L. 1, 2 (2014).

95. Tetty Havinga, *Private Regulation of Food Safety by Supermarkets*, 28 LAW & POL’Y 515, 518 (2006).

96. SPENCER HENSON & JOHN HUMPHREY, *FOOD & AGRIC. ORG., THE IMPACTS OF PRIVATE FOOD SAFETY STANDARDS ON THE FOOD CHAIN AND ON PUBLIC STANDARD-SETTING PROCESSES* (2009), <http://www.fao.org/3/a-i1132e.pdf>.

emerged due to (1) a shift in regulatory responsibility for food safety and quality to industry, (2) the increased international sourcing of products, (3) heightened consumer concerns over food safety resulting from foodborne illness outbreaks, and (4) changing consumer attitudes in relation to their interest in product features beyond food safety. The UK's Food Safety Act of 1990, a product liability law which gave suppliers responsibility for ensuring the safety of all foods, is an example of indirect regulation,⁹⁷ which was later adopted by the European Union.⁹⁸ Globalization created opportunities for retailers to demand contracts that could increase coordination, streamline their operation, reduce transaction costs, and harmonize their standards.⁹⁹ It also allowed retailers to offer foods with attributes beyond food safety (environmental, social, and animal welfare dimensions of food production processes) referred to as non-product-related production and process methods, which are typically discouraged by the WTO.¹⁰⁰ It became clear that by virtue of WTO membership, states were unable to regulate non-product-related production and process methods, while private standards could do so. As we shall later see, this one virtue of private schemes—their ability to sidestep WTO principles—cuts against their legitimacy. Nevertheless, the popularity that global schemes gained twenty years ago continues to this day as schemes grow in number and membership.

Schemes are not as visible in the United States as they are in Europe, where over 85% of all Western European retailers require GlobalGAP certification.¹⁰¹ Yet, scheme certification is a growing trend in the United States as more and more consumers are shopping in retail stores and expressing demand for certain product attributes. In the United States, consumers spend 64% of their food dollars on supermarket purchases, compared to 16.3% at warehouse clubs and supercenters,

97. Hugh Campbell et al., *Audit Culture and the Antipodes: The Implications of EurepGAP for New Zealand and Australian Agri-Food Industries*, in BETWEEN THE LOCAL AND THE GLOBAL: CONFRONTING COMPLEXITY IN THE CONTEMPORARY AGRI-FOOD SECTOR 71 (Terry Marsden & Jonathan Murdoch eds., 2006) (noting that section 21 of the 1990 Act provided a defense of due diligence where the defendant could prove that they took all reasonable precautions and exercised all due diligence to avoid committing that offense).

98. *Id.* See generally Ladina Caduff & Thomas Bernauer, *Managing Risk and Regulation in European Food Safety Governance*, 23 REV. POL'Y RES. 153 (2006).

99. Maki Hatanaka et al., *Third-Party Certification in the Global Agrifood System*, 30 FOOD POL'Y 354, 356 (2005).

100. Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 HARV. L. REV. 525 (2004).

101. GRACE CHIA-HUI LEE, EUR. COMM'N, PRIVATE FOOD STANDARDS AND THEIR IMPACTS ON DEVELOPING COUNTRIES 27 (2006), http://trade.ec.europa.eu/doclib/docs/2006/november/tradoc_127969.pdf.

5.9% directly at farms, processors, or wholesalers, 2.9% home delivered or mail order, 2.7% at convenience stores, 2.3% at specialty food stores and the remainder in other venues.¹⁰² When consumers demand specific quality attributes such as organic, free range, cage free, hormone free, grown without pesticides, or express concerns over fair trade, child labor, and overexploiting natural resources, retailers respond by regulating their transnational suppliers,¹⁰³ often requiring that their suppliers comply with a universally accepted auditing scheme.¹⁰⁴ The auditing scheme could include, for example, firm-specific guidelines on suppliers' abilities to perform a product recall or MRLs that exceed national standards by 25%–80%.¹⁰⁵

Of course, retailers may also require supplier compliance with a scheme for various other reasons: to increase coordination among food safety management activities all along the food chain, to strengthen the legal responsibility of food chain operators for the safety of food that they produce, to improve transparency and accountability for public food safety decision making,¹⁰⁶ or to market their products by offering conformity with global standards and in a way to engage in non-price competition.¹⁰⁷ For an early example of private-retailer-imposed certification: In 1999, Safeway, then the third largest food retailer, required all of their suppliers of certain commodities to verify, through third-party certification, that they follow Good Agricultural Practices for production and Good Manufacturing Practices for packinghouses for domestic and imported produce.¹⁰⁸ The Safeway example is

102. U.S. DEP'T OF AGRIC., FOOD EXPENDITURES: TABLE 14—SALES OF FOOD AT HOME BY TYPE OF OUTLET (INCLUDING SALES TAX) (2016), <http://www.ers.usda.gov/data-products/food-expenditures.aspx>.

103. See Havinga, *supra* note 95, at 521 (noting that grocery retailers respond to consumer preferences for food safety and quality and may set more stringent standards than public regulators).

104. GLOBAL FOOD SAFETY INITIATIVE [GFSI], ENHANCING FOOD SAFETY THROUGH THIRD PARTY CERTIFICATION (2011), http://www.mygfsi.com/gfsifiles/GFSI_White_Paper_-_Enhancing_Food_Safety_Through_Third_Party_Certification.pdf.

105. *Id.* at 2 (referencing the FAO Private Food Safety Standards).

106. In the past, retailers could escape liability through contracting; however, in recent years this has changed. See, e.g., Jennifer Brown, *Walmart Settles with Cantaloupe Victims from Colorado Outbreak*, DENV. POST (May 13, 2014, 5:22 PM), http://www.denverpost.com/news/ci_25755216/walmart-settles-cantaloupe-victims-from-colorado-outbreak.

107. Maki Hatanaka & Lawrence Busch, *Third-Party Certification in the Global Agrifood System: An Objective or Socially Mediated Governance Mechanism?*, 48 SOCIOLOGIA RURALIS 73 (2008), <http://onlinelibrary.wiley.com/doi/10.1111/j.1467-9523.2008.00453.x/full>.

108. Linda Calvin, *Produce, Food Safety, and International Trade: Response to U.S. Foodborne Illness Outbreaks Associated with Imported Produce*, in U.S. DEP'T OF AGRIC., INTERNATIONAL TRADE AND FOOD SAFETY 90 (Jean C. Buzby ed., 2004), http://www.ers.usda.gov/media/321547/aer828g_1_.pdf.

representative of the increasing phenomenon in the United States, European Union, and elsewhere, that each retailer has its own marketing channel with its own set of vendor agreements, compliance regulations, and costs. This is unique in two respects. First, unlike national governments, which are tied to WTO regulations and rules, retailers are free to draft buyer-driven requirements that can exceed national standards. Second, from a sociological perspective, the growing influence of the private sector in food safety means that the focus on the state for providing food safety is no longer adequate.¹⁰⁹

Whole Foods Market and Wal-Mart provide other examples of private retail standards. All suppliers to the Whole Foods chain must meet detailed standards that include: acceptable and unacceptable ingredients; storage and handling of products; and welfare standards for livestock providing meat, poultry, eggs, and dairy products.¹¹⁰ Another example is Wal-Mart's announcement of corporate-wide efforts to have fresh produce suppliers follow the Produce Traceability Initiative Protocol and institute a "100% money back" guarantee on freshness by 2014, with no mention of exemptions or exclusions for small farms or local produce.¹¹¹ Unlike governments, firms do not have to be fair or inclusive (described *infra*). For instance, standard vendor agreements that supermarkets use essentially serve as supplier contracts and often include provisions that supersede the small business exemptions proposed for the FSMA.¹¹² In other words, the contracts apply to all suppliers regardless of their size.

While there is wide variation in requirements among regional or national supermarket chains, understanding the difference between a standard and a scheme is fundamental to interpreting observed differences between Codex standards and private food safety schemes. As described earlier, food safety standards may be numerical (defining

109. Lawrence Busch & Jim Bingen, *Introduction: A New World of Standards*, in AGRICULTURAL STANDARDS: THE SHAPE OF THE GLOBAL FOOD AND FIBER SYSTEM 11 (Jim Bingen & Lawrence Busch eds., 2006).

110. WHOLE FOODS MARKET, WHOLE BODY SUPPLIER GUIDELINES, VERSION 2 (2013), http://www.wholefoodsmarket.com/sites/default/files/media/Global/Company%20Info/PDFs/Whole_Body_Supplier_Guidelines.pdf.

111. Rodney B. Holcomb et al., *Food Safety Policies and Implications for Local Food Systems*, 28 CHOICES, no. 4, 2013, at 1, 2, <http://www.choicesmagazine.org/choices-magazine/theme-articles/developing-local-food-systems-in-the-south/food-safety-policies-and-implications-for-local-food-systems>. See generally WALMART, FOOD SAFETY & HEALTH, FOOD SAFETY REQUIREMENTS FOR PRODUCE SUPPLIERS (2013), http://az204679.vo.msecnd.net/media/documents/food-safety-requirements-for-produce-suppliers_130042261618354678.pdf.

112. Even with small business exemptions from the FSMA, local producers are generally encouraged to follow Good Agricultural Practices ("GAP") and Good Handling Practices ("GHP") protocols.

required characteristics of products—such as contaminant limits or MRLs), or process oriented (defining how the food should be produced including verifiable performance objectives or defining the requirements of the management system such as documentation requirements). Supply chains may have their own standards in place, in the case of a supplier-buyer relationship like Wal-Mart, and this standard may or may not be benchmarked against a private global food safety scheme, which includes standards plus a governance structure for certification and enforcement of those standards. That scheme could exceed national food safety standards. For example, in 2008, Wal-Mart required retailers to provide real-time details on where suppliers fall short in food safety on a plant-by-plant basis,¹¹³ a process standard that exceeded current U.S. food safety requirements.¹¹⁴

Two examples, one from a supplier perspective and one from a retailer perspective, illustrate how certification schemes operate. Assume that Honeyville Food Products, a flour manufacturer from Salt Lake City, Utah, wants to supply flour to Panera Bread Restaurants. Panera agrees, but stipulates that Honeyville must achieve Safe Quality Food (“SQF”) Level 2 food safety certification, a certified Hazard Analysis Critical Control Protection food safety plan that is benchmarked by the Global Food Safety Initiative, or GFSI.¹¹⁵ The

113. In 2008, Wal-Mart became the first U.S. grocery chain requiring their factories to be certified against one of the internationally recognized Global Food Safety Initiative (“GFSI”) standards under which producers of Wal-Mart and Sam’s Club private label and other foods sold in the United States must be audited by independently trained, approved, and licensed auditors who are experts in their industry. Press Release, Wal-Mart, Wal-Mart Becomes First Nationwide U.S. Grocer to Adopt Global Food Safety Initiative Standards (Feb. 4, 2008), <http://news.walmart.com/news-archive/2008/02/04/wal-mart-becomes-first-nationwide-us-grocer-to-adopt-global-food-safety-initiative-standards>.

114. *Id.* A recent study of GFSI scheme compatibility with FSMA rules concluded that GFSI schemes are not only consistent with but sometimes exceed the FSMA rules. SUPREEYA SANSAWAT & JIM COOK, SGS, UNDERSTANDING THE US FOOD SAFETY MODERNIZATION ACT (FSMA) (2013), <http://www.apinews.com/en/news/item/download/1544>.

115. In many cases, customers designate a minimum level of certification. See *How to Achieve Certification*, SQF INST., <http://www.sqfi.com/suppliers/certification-steps/> (last visited Mar. 20, 2016). According to the website, there are over 4500 SQF-certified suppliers in the United States. Retailers that buy from certified suppliers are referred to as those that “support” SQF-certified-suppliers. Examples are: Kraft Foods, Subway, Target, Hershey, McDonalds-U.S., Sam’s Club, and Safeway Inc. *SQF Buyer Supporters*, SQF INST., <http://www.sqfi.com/buyers/sqf-buyer-supporters> (last visited Mar. 20, 2016). This is similar with other certifications. For instance, Primus GFS is another U.S.-benchmarking scheme. It has a long list of over 12,000 suppliers that are certified as of May 24, 2014. Buyers who support Primus certified suppliers include: Sysco Corporation, Costco Companies, Inc., Publix Super Markets, Inc., Sonic Drive In, Subway, and Wendy’s International, Inc. For a detailed list of buyers, see *Buyers Who Support Our Services*, PRIMUSLABS, <http://www.primuslabs.com/fsr/buyersList.aspx> (last visited Mar. 20, 2016).

SQF standard “creat[es] one standard for food safety from farm to fork.”¹¹⁶ To receive certification, Honeyville has to take many steps to ensure that it complies with the SQF standard, leading up to a third-party facility audit from a licensed SQF-approved auditor.¹¹⁷

A third-party audit is one in a series of three types of checks to ensure that a party complies with a standard. A third-party auditor that provides certification services is known as certification body, and is authorized to audit against a recognized scheme through a formal agreement with a scheme owner combined with the scope of their accreditation.¹¹⁸ Only third-party certifiers that have been accredited by accreditation bodies licensed by the scheme can certify supplier compliance with a scheme. Most third-party certifiers are accredited by an accreditation body that ensures that participating certification bodies in the country are subject to oversight by an authoritative body—one that sets standards and guidelines by which to audit companies, certify certification bodies to do the auditing, and continuously confirm that certification bodies and their employees follow the established standards.¹¹⁹ Certification bodies may be a part of many different accreditation bodies.¹²⁰ And finally, accreditation bodies operating in different markets may voluntarily join “accreditor associations” and submit to continuous auditing by them during their membership to ensure consistent standards.

Returning to the example, Honeyville uses the certification-body database on the SQF website to locate an SQF-approved auditor and hires NSF Food Safety Certification, LLC in Ann Arbor, Michigan, to conduct its SQF facility audit.¹²¹ If it passes the audit, Honeyville will be SQF-certified. This means that Honeyville will be able to supply to

116. See *A Certification for Every Link in the Food Chain*, SQF INST., <http://www.sqfi.com/standards/> (last visited Mar. 20, 2016).

117. See *How to Achieve Certification*, *supra* note 115.

118. See SQF INST., CRITERIA FOR SQF CERTIFICATION BODIES (7th ed. 2015), <http://www.sqfi.com/wp-content/uploads/Criteria-for-Certification-Bodies-1.16.15.pdf>. GFSI recognizes several schemes. Certification bodies may be as small as a few people, while some are transnational and have tens of thousands of employees. See *Recognised Schemes*, GFSI, <http://www.mygfsi.com/schemes-certification/recognised-schemes.html> (last visited Mar. 20, 2016).

119. See SQF INST., *supra* note 118.

120. For example, the National Sanitation Foundation International—one of the largest certification bodies in the world—is accredited by the Standards Council of Canada, the United Kingdom Accreditation Service, and the American National Standards Institute-American Society for Quality National Accreditation Board.

121. A search for SQF certifiers on the SQF website yielded thirty-five entries. See *Licensed Certification Bodies*, SQF INST., <http://www.sqfi.com/forms/membership/CertificationDirectoryPublic/searchLogos?action=Search> (last visited Mar. 20, 2016).

any retailer, in the United States and elsewhere, that accepts the SQF certification.

What if Honeyville wants to sell to a retailer in multiple markets (the United States, Germany, and the United Kingdom)? Is it safe to say that it would face multiple scheme requirements for each market—for example, SQF, GlobalGAP, and British Retail Consortium (“BRC”)? If so, the transaction costs to certify against multiple schemes could lead to audit fatigue. Using a GFSI-benchmarked scheme eliminates this fatigue. Because the SQF Level 2 certification is GFSI-benchmarked, Honeyville will also be able to supply to any retailer that requests SQF or any other GFSI-benchmarked certification. Government organizations worldwide have varying standards when it comes to certification, and this has led to both governments and companies desiring a more centralized certification body.¹²²

GFSI emerged in 2000 as an international food safety and traceability benchmarking effort by food industry leaders to provide a food safety global certification for suppliers (“once certified, accepted everywhere”).¹²³ While not a scheme itself (it does not carry out any certification or accreditation activities), and not a scheme-owner, GFSI recognizes schemes by assessing the food safety standards of the scheme and the governance and management structure of the food safety scheme owner (e.g., technical competence, safeguards against conflicts of interest, and procedures for accreditation bodies to oversee the certification bodies that audit and issue certifications under the food safety scheme). GFSI-benchmarked schemes include: GlobalGAP, BRC, SQF1000, SQF2000, and PrimusGFS.¹²⁴ The U.S.-based American National Standards Institute (“ANSI”) currently provides accreditation services for three GFSI-benchmarked food safety schemes: the GlobalGAP, BRC, and SQF schemes.¹²⁵ This means that ANSI accredits third-party certifiers under these scheme standards. For the supplier, certifying against a GFSI-recognized scheme means that: (1) it conforms to a global scheme standard, and (2) it meets internationally recognized minimum food safety requirements set out in the GFSI Guidance Document, developed by multiple stakeholders.¹²⁶

The above hypothetical featured Honeyville, an ingredient (flour)

122. Hatanaka et al., *supra* note 99, at 358.

123. See *Recognised Schemes*, *supra* note 118.

124. Clarke, *supra* note 48, at 7.

125. See Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. 45,782 (proposed July 29, 2013) (to be codified at 21 C.F.R. pts. 1, 16), <https://www.gpo.gov/fdsys/pkg/FR-2013-07-29/pdf/2013-17994.pdf>.

126. See *Recognised Schemes*, *supra* note 118.

manufacturer, navigating SQF certification as a prerequisite to a supply contract with Panera, a national restaurant chain. The example demonstrates how contracting with food processors, retailers, and foodservice entities ensures the safety of the supply chain. The only downside is that requiring individual schemes may not be as efficient as requiring a GFSI-benchmarked scheme. In 2008, Wal-Mart became the first national grocery chain to require suppliers to comply with GFSI-benchmarked schemes.¹²⁷ Prior to that point, one problem that Wal-Mart faced, along with every other retailer and food service company, was sourcing from essentially the same group of suppliers, which made the number of food safety audit requirements unmanageable.¹²⁸ Wal-Mart found that requiring suppliers of its private label and other food products to become certified against GFSI standards would not only ensure protection and confidence in the food supply, but also would reduce the number of audits and associated costs incurred by the supplier.¹²⁹ For Wal-Mart, the food safety benefits were realized two years later when it found, through an internal study, a 34% reduction in the number of recalls the company had executed across the same supplier base.¹³⁰

In recent years, when it comes to food safety, food processors, retailers, and foodservice entities have shown greater emphasis in the use of GFSI standards.¹³¹ Standards that combine food safety goals with other objectives are also popular (e.g., Kenya-GAP,¹³² ThaiQ, ChileCAP, Colombia Florverde, Ecuador's FlorEcuador,¹³³ Idaho Potatoes, and Florida Oranges), while others focus on promoting or rewarding sustainable or ethical business practices (e.g., IFOAM Basic Standard, Soil Association, East African Organic Standard, Rainforest Alliance, Bird-Friendly, Dolphin-Friendly, GMO-free, Conservation

127. Monica Watrous, *Wal-Mart's Food Safety Efforts Yield Lower Costs, Fewer Recalls*, *FOODBUSINESSNEWS* (June 3, 2013), http://www.foodbusinessnews.net/articles/news_home/Food_Safety_News/2013/06/Wal-Marts_food_safety_efforts.aspx?ID={28D4BA2B-1BF9-43D3-94D3-4EE36EB79A19}&cck=1.

128. *Id.*

129. *Id.*

130. *Id.*

131. Holcomb et al., *supra* note 111, at 3.

132. See *Kenya-GAP Successfully Re-benchmarked for GLOBALG.A.P. Integrated Farm Assurance Standard Version 4*, GLOBALG.A.P. (Jan. 22, 2014), http://www.globalgap.org/uk_en/media-events/news/articles/Kenya-GAP-Successfully-Re-benchmarked-for-GLOBALG.A.P.-Integrated-Farm-Assurance-Standard-Version-4/. Kenya-GAP is the only scheme in Africa that is benchmarked against GLOBALG.A.P. in Africa. It promotes and ensures the implementation of socially and environmentally sound production and marketing practices of Kenyan retailers' fresh produce.

133. GFSI, *supra* note 104 (referencing FAO Private Food Safety Standards).

Agriculture, and FLO, for sustainability; Bio-equitable, EcoCert, and SA-8000, for fair trade and labor rights; Halal and Kosher, for religious labels; and free-range chickens and eggs, for animal welfare).¹³⁴

In what ways do these standards exceed SPS-*plus* standards? All GFSI-recognized schemes, by their very nature, comply with the requirements in the Codex General Principles of Food Hygiene Code of Practice. Some scheme requirements exceed Codex guidelines to include: product specifications, product analysis, purchasing procedures, internal audit, and full product or ingredient traceability.¹³⁵ These additional requirements add robustness to the minimum requirements of food safety, and are viewed by the food industry as being important to food safety or, at least, highly desirable in order to ensure continuing compliance.¹³⁶ Importantly, because most GFSI-recognized schemes are not country-specific, schemes can sometimes exceed national rules. For instance, in some respects, SQF exceeds U.S. FSMA rules.¹³⁷

Finally, an added benefit to schemes is that, in addition to establishing higher food safety standards, they are reviewed and revised more regularly than the Codex guidelines and, therefore, attempt to address issues that are currently faced by the food industry such as incident management, food defense, and allergen management.¹³⁸

In sum, the GFSI standard makes economic sense—the Wal-Mart example suggests that it is cheaper and easier to comply with one set of standards, rather than many. For most retailers and producers, the GFSI system, and private standards that come with similar schemes, was out of reach before FSMA. Imports did not need to be pre-approved for

134. *Id.*

135. *See Recognised Schemes, supra* note 118.

136. *Id.*

137. *See* LEAVITT PARTNERS, SQF LEVEL 2—PROPOSED PREVENTATIVE CONTROLS COMPARISON MODULES 2 & 11 (2013), <http://www.sqfi.com/wp-content/uploads/SQF-Preventive-Controls-Comparison-FULL-REPORT-April-2013.pdf>. SQF contracted with Leavitt Partners to compare the elements of SQF Level 2 (specifically Modules 2 & 11) to the FDA proposed requirements. The analysis examined the two major features of the proposed FDA rule: the new preventive controls requirements that industries must comply with in order to implement the requirements of section 103 of FSMA, and the updated current Good Manufacturing Practices (current 21 C.F.R. pt. 110). SQF Level 2, which focuses on food safety, is a GFSI-benchmarked scheme that is increasingly recognized within the food industry. The document has a full comparative table. In sum, there are several areas addressed by SQF that have not been addressed in the proposed rule. Some items may be covered by existing regulations or are covered by FSMA and will be addressed in forthcoming regulations; however, other items were not contemplated or addressed by the proposed rule or other aspects of FSMA. SQF extends beyond FSMA.

138. *See Recognised Schemes, supra* note 118.

entry; foreign producers were only penalized for noncompliance with Food and Drug Administration (“FDA”) rules if their shipment failed a randomly assigned border inspection, post-entry. What FSMA attempts to do is to certify that products are safe, pre-entry. Only the most forward-looking companies sought out higher standards and requiring GFSI standards would not have been possible in a command-and-control, pre-FSMA era, where regulators would have had to draft and enforce higher standards. With the introduction of FSMA, regulators draft standards, then ask suppliers to certify against those standards (or higher standards) and let private bodies complete the certifications. In contrast to a command-and-control economy, in this New Governance model, the federal government is not performing the certifications. While this Section focused on presenting the different regulation methods, from command-and-control regulation to cooperative regulation found in New Governance, the following Section explores implementing these methods.

II. HOW TO REACH THE “TOP SHELF”

When considering where to set food safety standards, countries have a range of options. A country chooses where it lands on the food safety table based on economic and political factors, which depend, in part, on border inspection capability and international agreements.¹³⁹ Some countries only can follow Codex; others can do more. Countries can reach for higher standards and stay within their constraints, I argue, by adopting New Governance strategies.

This Article urges a transition from a global food safety regime, characterized by command-and-control regulation, to a new regulatory paradigm, with New Governance at the center of the table. The new approach taken by FSMA and other countries (the Netherlands, the United Kingdom, and Canada¹⁴⁰) is to decentralize food safety regulation and collaborate with supply chains, nongovernmental organizations,¹⁴¹ and state actors.¹⁴²

139. See *supra* Table 1.

140. See Verbruggen & Havinga, *supra* note 11, at 6–7 (noting that public authorities in the Netherlands, the United Kingdom, and Canada have recently started to develop forms of coordination and collaboration with private food safety control systems).

141. *The Best of Food Safety: Non-Government Organizations*, FOOD SAFETY NEWS (Feb. 22, 2013), <http://www.foodsafetynews.com/2013/02/the-best-of-food-safety-non-government-organizations/#.VX288IF2h0A> [hereinafter *Food Safety*] (listing leading food safety NGOs).

142. See Lytton & McAllister, *supra* note 27 (mentioning no black or white dichotomy; there is middle ground); see also Christine Parker & John Braithwaite, *Regulation*, in *THE OXFORD HANDBOOK OF LEGAL STUDIES* 119 (Peter Cane & Mark Tushnet eds., 2003).

While New Governance is not new in other areas, it is new in the context of food safety. New Governance has been successful in environmental law,¹⁴³ occupational safety, discrimination law, and organizational sentencing guidelines,¹⁴⁴ where institutional culture and design have a significant impact on the likelihood of deterring unlawful action.¹⁴⁵ Mindful of its track record in different fields, food safety regulators question whether the potential for New Governance innovations will be offset by added challenges to an already stressed food safety system.¹⁴⁶ The following Sections describe U.S. rules as New Governance “in action,” introduce the key drivers behind New Governance, and present opportunities and perils in their application.

A. *The U.S. Example (Food Safety Modernization Act)*

The FSMA aims to increase food safety by focusing on preventing foodborne illness and contaminants in both domestic and imported food. The FSMA can be considered New Governance “in action,” because the proposed rules, as drafted, adopt key features of New Governance. Notably, FSMA’s import-safety provisions focus on leveraging: (1) the use of third-party certification and voluntary standards,¹⁴⁷ and (2) cooperative relationships with other governments.¹⁴⁸ Engaging private actors and public-private partnerships are key elements of New Governance understanding and food safety governance.¹⁴⁹ I, first, turn to third-party certification and voluntary standards.

As noted earlier, fifty years ago, consumers placed great trust in grocers and government agencies to certify that foods were safe to

143. See generally Michael P. Vandenbergh, *Private Environmental Governance*, 99 CORNELL L. REV. 129, 162–99 (2013).

144. For a description of New Governance as applied to other legal disciplines, see Lobel, *supra* note 25.

145. *Id.* at 420.

146. See Lytton & McAllister, *supra* note 27, at 297–304 (discussing the problems with third-party certification if not structured correctly).

147. See 21 U.S.C. § 384d (2012) (requiring the Secretary to establish a system for the recognition of accreditation bodies that accredit third-party auditors by two years after enactment); see also *id.* § 384a (requiring the U.S. owner or consignee of an imported food at the time of entry to verify that the food was produced in compliance with U.S. rules and is not adulterated, in all likelihood requiring third-party certification); *id.* § 384b (providing for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in a program that requires certification).

148. See FSMA, H.R. 2751, 111th Cong. § 305 (2011). For a description of the current agreement with New Zealand and the pilot project with Canada, see *FDA Recognizes New Zealand as Having a Comparable Food Safety System*, U.S. FOOD & DRUG ADMIN. (Dec. 13, 2012), <http://www.fda.gov/food/newsevents/constituentupdates/ucm331276.htm>.

149. See Lytton & McAllister, *supra* note 27, at 296 (discussing the role of private actors in food safety governance).

eat.¹⁵⁰ Today, supply chains are long and diffuse and most of the qualities that consumers demand cannot be tested once the product has been placed on the grocery store shelf. While food can be tested for pesticides, it is nearly impossible to discern whether a product is organic, if it has been made using child labor, or if the workers involved in the production were paid fair wages.¹⁵¹ From an economic perspective, consumers demand food safety and governments try to provide it. Yet, as consumers search for a range of attributes and assurances, governments struggle to ensure the safety of foods coming from a massive and growing food industry. Ultimately governments realize that they need additional resources to manage and certify the broad range of industries and certifications.¹⁵²

The use of third-party certification¹⁵³—independent onsite auditing of a facility or process leading to a certification—is a rapidly growing private-sector practice that provides consumers with a level of trust that existed long ago when one purchased directly from the farmer.¹⁵⁴ FSMA sections 302 and 303 give the FDA authority to use certifications issued by accredited third-party auditors¹⁵⁵ for two purposes. First, FSMA section 302 authorizes the FDA to create Voluntary Qualified Importer Protection, a voluntary, fee-based program that provides for expedited review and importation of foods from certified facilities.¹⁵⁶

150. Hatanaka et al., *supra* note 99. The first consumer protection law was passed in the United States in 1813, which became really enforced after Upton Sinclair's acclaimed novel, *The Jungle*, and the resulting Pure Food and Drug Act of 1906. See generally John P. Swann, *FDA's Origin*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm> (last updated June 23, 2014).

151. See Friederike Albersmeier et al., *The Reliability of Third-party Certification in the Food Chain: From Checklists to Risk-Oriented Auditing*, 20 FOOD CONTROL 927 (2009).

152. *Id.*

153. See Press Release, Union of Orthodox Jewish Congregations of Am., Heinz to be Honored for Being First Company to Debut Kosher Symbol (May 25, 1999), <https://archive.is/rNwFX> (noting that the first third-party certification was the kosher label, used by the Orthodox Union, a non-profit organization, in 1923). See generally TIMOTHY D. LYTTON, *KOSHER: PRIVATE REGULATION IN THE AGE OF INDUSTRIAL FOOD* (2013).

154. See Hatanaka et al., *supra* note 99.

155. The rule on accreditation of third-party auditors: “[A] third-party auditor can be a foreign government, an agency of a foreign government, a foreign cooperative, or any other third party” Accreditation of Third-Party Auditors Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 80 Fed. Reg. 74,570, 74,585 (proposed Nov. 27, 2015) (to be codified at 21 C.F.R. pts. 1, 11 & 16). It must also meet standards for “legal authority, competency, capacity, conflicts of interest, quality assurance, and records.” See *id.* at 74,586.

156. See 21 U.S.C. § 384b (2012) (providing “for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such program”); see also *id.* § 381(a) (providing that the Secretary of the Treasury must deliver to the Secretary of Health and Human Services samples of food, drugs, devices, tobacco products, and cosmetics that are being imported or offered for import into the United States).

This program is designed for importers who achieve and maintain a high level of control over the safety and security of their supply chains.¹⁵⁷ Second, FSMA section 303 gives the FDA authority to require that high-risk imported foods be accompanied by a credible third-party certification or other assurance of compliance as a condition of entry into the United States.¹⁵⁸

While these two rules require onsite audits performed by a qualified third-party auditor, other rules are likely to accept third-party audits for verification purposes. The Foreign Supplier Verification Program (“FSVP”), for instance, requires importers to perform risk-based, foreign-supplier verification activities to ensure that foreign suppliers have adequate preventive controls in place.¹⁵⁹ Although the FSVP proposal does not require the use of accredited third-party auditors, the FDA anticipates that once the FDA accreditation system is in place, importers may increasingly rely on audits by accredited third parties to meet their supplier verification requirements under FSVP.¹⁶⁰ Interestingly, food producers have sought out higher standards for imports, showing how supply chains influenced FSMA.¹⁶¹ All versions

157. See *id.* § 384d; see also *New FDA Program Will Benefit Both Importers and Consumers*, U.S. FOOD & DRUG ADMIN. (June 4, 2015), <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm448567.htm> (noting that the program is expected to be open for applications in January 2018 to allow enough time for a facility to be certified under the FDA’s Accredited Third-Party Certification program).

158. See 21 U.S.C. § 381(a).

159. See *id.* § 384a (stating verification activities under this program may include: monitoring records for shipments; lot-by-lot certification of compliance; annual on-site inspections; checking the hazard analysis and risk-based preventive control plan of the foreign supplier; and testing and sampling).

160. Accreditation of Third-Party Auditors Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 80 Fed. Reg. 74,570, 74,585 (proposed Nov. 27, 2015) (to be codified at 21 C.F.R. pts. 1, 11 & 16).

161. See *FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm> (last updated Feb. 25, 2016) (noting that the revisions that the FDA proposed included providing importers the flexibility to determine appropriate verification measures based on food and supplier risks, while acknowledging the greater risk to public health posed by the most serious hazards in foods). Regarding the requirements for supplier verification activities, the FDA suggests:

When there is reason to believe that a hazard in a food that will be controlled by the foreign supplier is one for which there is a reasonable probability that it will cause serious adverse health consequences or deaths, a clear, rigorous verification standard is required in the form of annual on-site auditing of the supplier. However, importers have the flexibility to use a different approach if they can establish that it will be appropriate to provide adequate assurance that the foreign supplier is significantly minimizing or preventing the hazard.

Frequently Asked Questions on FSMA, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm> (last updated Feb. 19, 2016).

of the rule contain language that the FDA carefully considered using Codex guidelines on food import control systems on the use of third-party auditing for food safety:

In describing the general characteristics of food import control systems, the Guidelines for Food Import Control Systems developed by the Codex Committee on Food Import and Export Inspection and Certification Systems recognize a number of related concepts, including: that countries can set their own appropriate levels of protection; that standards should be based on risk and, as far as possible, applied equally to imported and domestic food; that there is a potential need for different approaches to compliance monitoring of domestic and imported food to ensure consistent levels of protection; and that there is utility in conducting audits, along with using other tools, in addition to assessing importer controls to ensure that imported foods are safe, including importers' use of supplier verification systems.¹⁶²

Finally, FSMA highlights flexibility and voluntary initiatives, two New Governance features. The FSVP allows importers to verify that exporters comply with U.S. rules in various ways, thus providing importers with great flexibility;¹⁶³ and further, the Voluntary Qualified Importer Protection program grants expedited entry for certified foods at a completely voluntary level.

Next, I turn to the FSMA's import-safety provisions, which focus on cooperative relationships with other governments. Section 305, "Building Capacity of Foreign Governments with Respect to Food Safety," directs the FDA to consider bilateral and multilateral agreements, including provisions, under specific situations, to specify the responsibility of countries for the safety of food they export.¹⁶⁴ System Recognition is one such program.

Technically a Memorandum of Understanding, or MOU, between two countries, System Recognition is sanctioned by the WTO¹⁶⁵ and goes beyond bilateral agreements in place.¹⁶⁶ Through System Recognition, the FDA seeks to leverage the work done by foreign

162. Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 78 Fed. Reg. 45730, 45741 (proposed July 29, 2013) (to be codified at 21 C.F.R. pt. 1), <https://www.gpo.gov/fdsys/pkg/FR-2013-07-29/pdf/2013-17993.pdf> (citations removed).

163. See 21 U.S.C. § 384a.

164. See FSMA, H.R. 2751, 111th Cong. § 305 (2011).

165. See Brunet Marks, *supra* note 30; see also WORLD TRADE ORG., THE WTO AGREEMENTS SERIES: SANITARY AND PHYTOSANITARY MEASURES (2010), http://www.wto.org/english/res_e/booksp_e/agrmtseries4_sps_e.pdf.

166. While it is beyond the scope of this Article to examine the extent to which systems recognition agreements advance beyond previous bilateral agreements and to compare the bilateral agreements with SPS plus features, this is certainly ripe for future study.

competent authorities to help ensure the safety of imported foods. The FDA also gives itself the leeway to work “directly with an export certification program of another country, develop bilateral commodity-specific arrangements, or develop protocols, agreements, or other arrangements regarding export certification programs.”¹⁶⁷ Negotiating these coordinated agreements is a strategy to extend national (U.S.) law and exert regulatory pressure consistent with the WTO. Through the use of third-party certification, voluntary standards, and cooperative agreements, the FSMA agreement codifies elements of New Governance, and serves as an example of New Governance “in action.”

B. *Using New Governance Versus Traditional Governance*

The FSMA rules codify a new era in regulating food imports, which can be viewed as a regulatory transition from command-and-control regulation to New Governance.¹⁶⁸ As noted earlier, the phenomenon of New Governance refers to a regulatory paradigm defined by privatization, decentralization, public participation, horizontal coordination, experimentation, and a solution-oriented focus.¹⁶⁹ Professor Orly Lobel describes such public-private collaborations as systems in which individuals are “norm-generating subjects.”¹⁷⁰ In this way, a New Governance regime can be understood as a departure from a command-and-control model at its very essence, as it is more “bottom-up” in nature.¹⁷¹ At a basic level, New Governance is a tool orchestrated by the government to engage other public, private, and nongovernmental entities in co-regulation. The central elements of New Governance can be narrowed down to four in which the state:

167. *Information for Foreign Governments: Frequently Asked Questions on Systems Recognition*, U.S. FOOD & DRUG ADMIN. (Sept. 5, 2013), <http://www.fda.gov/Food/International/InteragencyCoordination/ucm367400.htm> (discussing the FDA System Recognition Program).

168. FSMA rules presumably have their origins in literature on import safety. See IMPORT SAFETY: REGULATORY GOVERNANCE IN THE GLOBAL ECONOMY (Cary Coglianese, Adam M. Finkel & David Zaring eds., 2009) (paying particular attention to Part IV, *Leveraging the Private Sector*—including, Kenneth A. Bamberger & Andrew T. Guzman, *Importers as Regulators: Product Safety in a Globalized World*; Errol Meidinger, *Private Import Safety Regulation and Transnational New Governance*; and David Zaring & Cary Coglianese, *Delegated Governance: Consumer Safety in the Global Marketplace*—for discussion on how solutions for import safety point to delegated forms of governance to enhance consumer protection).

169. See Lobel, *supra* note 25; see also Cohen, *supra* note 26 (discussing the experimentation thread of New Governance).

170. See Orly Lobel, *New Governance as Regulatory Governance*, OXFORD HANDBOOK GOVERNANCE, Nov. 2012, at 1, 5.

171. See Jason M. Solomon, *Law and Governance in the 21st Century Regulatory State*, 86 TEX. L. REV. 819, 821–23 (2008) (book review) (noting that new governance is more focused on learning through monitoring than “compliance with fixed rules”).

1. incorporates a decentralized range of actors and institutions, both public and private, into the regulatory system, as by negotiating standards with firms, encouraging and supervising self-regulation, or sponsoring voluntary management systems;
2. relies on this range of actors for regulatory expertise;
3. modifies its regulatory responsibilities to emphasize orchestration of public and private actors and institutions rather than direct promulgation and enforcement of rules; and
4. utilizes “soft law” to complement or substitute for mandatory “hard law.”¹⁷²

New Governance can also be understood as a scholarly effort to bring together two distinct academic literatures: empirical studies of regulation and normative thinking about the role of the state.¹⁷³ In *Law and Governance in the 21st Century Regulatory State*, John Solomon succinctly explains the essential shortcoming of the command-and-control regulatory model in today’s world. “In a world of uncertainty,” Solomon states, “legislatures and agencies are unable to predict what the best rules will be down the road, and the mechanisms for monitoring and adjusting the rules in light of experience are severely lacking.”¹⁷⁴ This has led to the need to consider and adopt alternative approaches to regulation. Solomon describes New Governance as “centrally coordinated local problem solving” guided by “provisionality and revisability in light of experience.”¹⁷⁵ The solution-based focus of New Governance is in opposition to the deeply engrained tendency of the judiciary to find the *meaning* of texts rather than the *solutions* to problems (a tendency New Governance scholar Michael Dorf attributes to the “cut[ting] of the link” between abstract normative propositions and natural, observable law).¹⁷⁶ Finally, Solomon makes another important point in that New Governance efforts in the United States versus those in the European Union differ; efforts in the United States have been cultivated from the bottom up (often “originating either

172. Abbott & Snidal, *supra* note 10, at 509 (emphasis omitted); *see also* Lobel, *supra* note 25, at 371–404 (noting eight organizing principles).

173. Lobel, *supra* note 25.

174. Solomon, *supra* note 171, at 822; *see also* J.B. Ruhl, *Regulation by Adaptive Management—Is it Possible?*, 7 MINN. J.L. SCI. & TECH. 21, 25 (2005) (noting that we have no idea what response the regulation model system would exhibit to any particular command).

175. Solomon, *supra* note 171, at 823 (quoting Susan Sturm, *Gender Equity Regimes and the Architecture of Learning*, in *LAW AND NEW GOVERNANCE IN THE EU AND THE US* 323, 323 (Grainne de Búrca & Joanne Scott eds., 2006); and Grianne de Búrca & Joanne Scott, *Introduction: New Governance, Law and Constitutionalism*, in *LAW AND NEW GOVERNANCE*, *supra*, at 1, 3).

176. Michael C. Dorf, *The Supreme Court, 1997 Term—Foreword: The Limits of Socratic Deliberation*, 112 HARV. L. REV. 4, 35–39 (1998).

within administrative agencies or from particular institutional actors”) while many of those in Europe have been developed through funding coming from the European Union.¹⁷⁷ This distinction is critical because much of the scholarship on New Governance examines and analyzes systems that have been implemented in Europe.¹⁷⁸

In practice, New Governance has not always been a wholesale shift in regulatory methodology. In some instances, New Governance principles coexist with principles normally seen in a command-and-control regulatory model.¹⁷⁹ In the European Union, for example, the Water Framework Directive is a *hybrid* form of government featuring characteristics of both New Governance and traditional governance in order to maximize its efficacy.¹⁸⁰ The main New Governance attributes of this directive are horizontal coordination (in the form of information sharing) and public participation, with binding legal regulation from member states as a traditional regulatory feature.¹⁸¹ In the United States, New Governance principles have been used to help minimize costly tort litigation in medical malpractice. In order to “deter negligent conduct,” this system

uses such new governance techniques as “regulation by information” through the publication of data on physicians’ results, fiscal incentives for good performance by hospitals and clinics, alternative forms of victim compensation through administrative processes similar to workers compensation, and conflict avoidance through informal methods to explain and apologize for error.¹⁸²

Another project in the United States is Green Tier, a Wisconsin program that promotes innovative strategies developed by regulated entities that allows companies to “opt out of a variety of environmental regulations if they agree to construct a self-regulatory regime and use it to achieve higher standards of environmental performance that is required under existing regulations.”¹⁸³ As Louise and David Trubek explain, having the standard regulatory framework in place motivates these entities to self-regulate, while the opportunity to opt out allows them to create innovative approaches to ultimately enhance regulatory

177. Solomon, *supra* note 171, at 823–24.

178. See generally *id.*; Marian Garcia Martinez et al., *Co-regulation as a Possible Model for Food Safety Governance: Opportunities for Public-Private Partnerships*, 32 FOOD POL’Y 299 (2007); David M. Trubek & Louise G. Trubek, *New Governance & Legal Regulation: Complementarity, Rivalry, and Transformation*, 13 COLUM. J. EUR. L. 1, 9–19 (2006).

179. See Trubek & Trubek, *supra* note 178, at 5–21.

180. *Id.* at 15–18.

181. *Id.*

182. *Id.* at 10.

183. *Id.* at 20.

efficacy.¹⁸⁴

Given these examples of co-production, nations can use New Governance to achieve food safety benefits typically provided by private governance. In some ways, the FSMA is a wholesale shift in regulatory methodology. Embracing private third-party certification to certify imports before they reach our ports is new and it certainly engages private actors to co-regulate. In other ways, however, it uses command and control; system integration agreements intentionally rely upon other public actors for expertise while they are negotiated as traditional bilateral agreements with other public actors.

So far, examples have highlighted primarily domestic New Governance models. It is useful to note the existence of another New Governance framework that recognizes the potential of New Governance for the international system. Abbott and Snidal develop a framework for adapting the domestic New Governance model of regulation to the international setting.¹⁸⁵ The authors argue that the rapid multiplication of regulatory standard-setting initiatives, mostly between public and private parties, is creating a new kind of transnational regulatory system, one that demands a broader view of regulation and a more nuanced view of the state as a regulator.¹⁸⁶ States and intergovernmental organizations are at the center of their framework, trying to orchestrate or provide a wide range of directive and facilitative measures designed to support and steer private and public actors to the regulatory system.¹⁸⁷ The way in which the FSMA applies New Governance features—principally through embracing third-party certification and bilateral agreements on food safety—may be considered an example of “Transnational” New Governance. Abbott and Snidal note that with New Governance, states can more easily organize actors because New Governance focuses on state orchestration, dispersed expertise, soft law, and decentralization, whereas

184. *Id.*

185. *See* Abbott & Snidal, *supra* note 10. In their framework, Abbott and Snidal present a “governance triangle” with many standard-setting schemes inside the triangle; inside, schemes can be aligned to one of three corners: States, NGOs, and Firms. In this Article, I focus on State practices (the United States), Firm practices (Schemes), and NGO practices (CODEX and WTO). I omit the study of organizations that are hybrid NGO-Firms, which in the food area include: the International Federation of Organic Agriculture, Fairtrade Labeling Organization, and Common Code for the Coffee Community, social, environmental standard, to name a few. Mapping out a Governance Triangle with respect to food safety would be a worthwhile exercise to fully understand the potential conversations between and contributions of the various food safety actors.

186. *See id.* at 506.

187. *Id.* at 510.

Transnational New Governance focuses on limited state orchestration, and even more dispersed expertise, voluntary codes, and decentralization.¹⁸⁸ The authors suggest how states can organize actors and intergovernmental organizations in the Transnational New Governance framework to support and steer the regulatory standard-setting schemes.¹⁸⁹

While the Transnational New Governance system establishes a framework that is applicable to food safety, there are some key distinctions. FSMA is doing exactly what Abbott and Snidal suggest, “extend[ing] a major domestic New Governance approach to the international plane by relaxing legal and administrative requirements for firms that adhere to approved transnational regulatory standard-setting schemes and require adherence by their suppliers.”¹⁹⁰ But, under Transnational New Governance, the state has limited involvement; whereas under FSMA, the state continues to play a significant role in orchestrating the alignment of public-private contacts. For instance, under FSMA, private actors (exporters) are encouraged to seek certification for their exported products by incentives such as the Voluntary Qualified Importer Program—which provides expedited entry for certified foods for approved exporters.¹⁹¹ To summarize, although the FSMA rules contain elements of Transnational New Governance, the rules most closely resemble an attempt to incorporate New Governance features into a traditionally command-and-control governance framework. The following Section introduces the “lessons learned” from using New Governance.

C. New Governance: Lessons Learned

Given that New Governance has been tried and tested with varying levels of success in other fields,¹⁹² it becomes useful to examine these experiences to identify opportunities and pitfalls for regulators implementing New Governance features. Because third-party certification is a prototypical example of New Governance, the focus here is on implementing a third-party certification program.

188. *Id.*

189. *Id.* at 511.

190. *Id.* at 565.

191. FSMA, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 21 U.S.C.)

192. See Gordon Hayburn, *Challenges for Auditing and Food Safety Management Systems: A Point of View*, 134 PERSP. PUB. HEALTH 196, 197 (2014) (noting that the United Kingdom, Canada and the United States recognize the value of the third-party audit through ideas like earned recognition in the United Kingdom, Canada’s Safe Food For Canadians Act, and the FSMA).

1. Opportunities

Using third-party certification can bring specific benefits. It is first useful to note that third-party certification is not new to U.S. regulators. Successful third-party certification programs have been mandated by legislation, and still others have been run by the FDA. For instance, in 1992, the Mammography Quality Standards Act required the FDA to approve accreditation bodies to evaluate and accredit mammography facilities based upon quality standards.¹⁹³ As referenced in the proposed FSMA rules, under the Mammography Quality Standards Act, only facilities that were accredited by an FDA-approved accreditation body received approval to legally perform mammography.¹⁹⁴ In 2008, Congress enacted the Consumer Product Safety Improvement Act requiring children's products to be tested by an approved third-party laboratory to certify compliance with product safety rules.¹⁹⁵ The Consumer Product Safety Commission approves accreditation bodies to accredit qualified third-party laboratories to test and certify products. Over 400 approved laboratories around the world test and certify imported and domestically manufactured products.¹⁹⁶ In 2010, Congress enacted the Formaldehyde Standards for Composite-Wood Products Act to address concerns about the public's exposure to formaldehyde emissions from manufactured products and building materials.¹⁹⁷ The EPA's third-party certification framework, modeled on California's program for verifying compliance with emissions limits, involves the EPA approving accreditation bodies to accredit qualified third-party certifiers.¹⁹⁸

In terms of specific benefits, the literature suggests that introducing private third parties to conduct regulatory duties such as third-party certification can provide five key benefits: (1) gatekeeping and monitoring expertise, (2) enhanced credibility and information sharing, (3) cost savings, (4) food safety gains, and (5) gaining industry

193. Mammography Quality Standards Act, Pub. L. No. 102-539, 106 Stat. 3547 (1994).

194. *See* Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. 45,782, 45786 (proposed July 29, 2013) (to be codified at 21 C.F.R. pts. 1, 16) (referring to Mammography Quality Standards Act provisions).

195. Consumer Product Safety Improvement Act, Pub. L. No. 110-314, 122 Stat. 3016 (2008).

196. U.S. FOOD & DRUG ADMIN., *supra* note 3.

197. Formaldehyde Standards for Composite Wood Products Act, Pub. L. No. 111-199, 124 Stat. 1359 (2010); *see also* Katie Greenhaw, *Growing Use of Third Parties to Certify Health and Safety Compliance Raises Troubling Questions*, CTR. FOR EFFECTIVE GOV'T (Sept. 24, 2013), <http://www.foreffectivegov.org/growing-use-third-parties-certify-health-and-safety-compliance-raises-troubling-questions>.

198. *Id.*

cooperation and reducing the regulatory burden.¹⁹⁹ The examples below are drawn from country examples (the Netherlands, the United Kingdom, and Canada) as well as industry examples in technology law, consumer protection law, and agricultural law.

Gatekeeping and Monitoring Expertise. Third-party certification can provide a function that governments may be failing in—the ability to use third-party certifiers as “gatekeepers” rather than mere deterrence. For example, there are instances where foreign firms say they have a Hazard Analysis Critical Control Point plan, or HACCP,²⁰⁰ in place but either the foreign firm is actually not following it, or FDA regulators have failed in overseeing it through onsite audits.²⁰¹ Third-party certification will ensure that companies claiming to have a safety plan or a HACCP plan actually have one in place. Third-party certification also provides the ability to utilize the monitoring expertise that industries have developed through the common practice of having voluntary certification schemes in place.

Enhanced Credibility and Information Sharing. From a business-oriented perspective, third-party certifications provide credibility, information, and quality assurance to customers. Using the 2008 Chinese Infant Formula Scandal as an example, evidence suggests that consumers of foods grown and manufactured in China would have greater confidence in those products if China were to allow a wider range of certifiers and labs to operate in China,²⁰² and if government-sponsored tests and certifications could be verified by private-sector third parties.²⁰³ Third-party certifications can also provide companies

199. See generally Hatanaka et al., *supra* note 99; Lytton & McAllister, *supra* note 27; Lesley K. McAllister, *Regulation by Third-Party Verification*, 53 B.C. L. REV. 1 (2012).

200. FSMA “Preventative Measures” require food producers to develop and maintain a food safety management system based on the principles of HACCP, a Codex standard.

201. See U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-11-286, SEAFOOD SAFETY: FDA NEEDS TO IMPROVE OVERSIGHT OF IMPORTED SEAFOOD AND BETTER LEVERAGE LIMITED RESOURCES 14–16 (2011), <http://www.gao.gov/assets/320/317734.pdf>.

202. FRED GALE & JEAN C. BUZBY, U.S. DEP’T AGRIC., ECON. INFO. BULLETIN NO. 52, IMPORTS FROM CHINA AND FOOD SAFETY ISSUES 23–24 (2009), http://www.ers.usda.gov/media/156008/eib52_1_.pdf (noting that the HACCP certification for Chinese exporters is performed by provincial quarantine bureaus).

CQC, China’s largest certification agency, also performs HACCP certifications, as well as organic, GAP, ISO 9000, and other certifications. CQC is nominally an independent entity but was a branch of [the General Administration of Quality Supervision, Inspection and Quarantine (China’s administrative agency in charge of overseeing food safety operations)] until 2002. [Studies have found] that water quality testing in China was beset by technical problems, funding and manpower shortages, and selective testing or manipulation of data by officials.

Id. at 24.

203. *Id.*; see also Alexandra Stevenson & Paul Mozur, *China’s Long Food Chain Plugs In*,

with a competitive edge on rival companies, as certification through a third-party organization creates a premium on products.²⁰⁴ Finally, giant food retailers, who have collectively chosen to obtain products from the same centralized procurement centers, use third-party certifications as a way to mitigate the risk of reputation damage from a foodborne illness outbreak that cannot definitively be traced to a single isolated store.²⁰⁵

Third-party certification provides the ability to keep up with the growing data needs involved in market-based regulation. As noted earlier, an added benefit to food safety schemes (which require third-party certification) is that, in addition to establishing higher food safety standards, schemes are reviewed and revised more regularly than the Codex General Principles of Food Hygiene Code of Practice; therefore, they attempt to address issues that are currently faced by the food industry such as incident management, food defense, and allergen management.²⁰⁶

Cost Savings. There is evidence that governments save money when they use third-party certifications,²⁰⁷ but only when governments do not become accreditation bodies themselves. Third-party certification provides the ability to shift regulatory costs to the regulated entity—suppliers incur the cost of certification—which has proven to be a great advantage for regulators. In 2014, in the midst of budget cuts, the Netherlands launched a program to coordinate food safety as a shared responsibility (co-regulation) between public and private actors.²⁰⁸ The Netherlands Food and Consumer Product Safety Authority deployed a strategy to assess and monitor the function of private third-party certifiers to use in its own enforcement activities. The Authority approved eleven “self-control” systems in food production, catering, and retail industries and used the systems and their audit results to determine inspection frequency, inspection length, and firm-specific interventions. The process was termed “meta-regulation,” a concept

N.Y. TIMES (Mar. 1, 2015), <http://www.nytimes.com/2015/03/02/business/international/chinas-long-food-chain-plugs-in.html> (noting that despite efforts to place certificates on food items and certifying the quality of the supply chain, consumers do not trust certificates of quality claiming that they can be “faked”).

204. B. James Deaton, *A Theoretical Framework for Examining the Role of Third-Party Certifiers*, 15 FOOD CONTROL 615 (2004).

205. Hatanaka et al., *supra* note 99, at 358–59.

206. *See Recognised Schemes*, *supra* note 118 (discussing GFSI-recognized schemes).

207. *See* Watrous, *supra* note 127 (discussing Wal-Mart’s cost savings, as well as food safety gains, when it introduced a GFSI-benchmarked certification system).

208. *See* Verbruggen & Havinga, *supra* note 11, at 6 (introducing the drivers for meta-control in the Netherlands).

that concerns the activity of “regulating the regulators, whether they be public agencies, private corporate self-regulators or third-party gatekeepers.”²⁰⁹ The findings show that in times of budgetary constraints, collaborating with private assurance schemes can be a cost-effective alternative to reduce inspection costs while maintaining inspection coverage.

Food Safety Gains. To my knowledge, FDA regulators were not cognizant that considering third-party certification and moving away from traditional regulation was a step toward embracing New Governance. There is evidence, however, that they were aware that considering third-party certification and moving away from traditional regulation was a step toward enhanced food safety. In 2004, based on a conclusion that seafood imports were unsafe to eat, the General Accounting Office issued a seafood safety report recommending that the FDA explore the possibility of certifying third parties to conduct inspections of foreign seafood processors and domestic importers, similar to the FDA’s third-party inspection program for medical devices.²¹⁰ Then, in 2008, a program referred to as the Shrimp Pilot was launched to examine the potential FDA use of third-party certification.²¹¹ The Shrimp Pilot succeeded in teaching the FDA that third-party certification could lead to gains in screening imports and that direct accreditation, in which the FDA accredits and provides direct oversight to third-party certification bodies, would be “costly and administratively burdensome.”²¹² Ultimately, the FDA decided to include the use of third-party audits as a part of import controls in FSMA.²¹³

Third-party certification schemes have been shown to enhance food safety. Increased compliance with food safety laws was one outcome noted by the Netherlands Food and Consumer Product Safety Authority.

209. *See id.*

210. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-04-246, *FOOD SAFETY: FDA’S IMPORTED SEAFOOD SAFETY PROGRAM SHOWS SOME PROGRESS, BUT FURTHER IMPROVEMENTS ARE NEEDED* (2004).

211. Voluntary Third-Party Certification Programs for Imported Aquacultured Shrimp; Notice of Pilot Program, 73 Fed. Reg. 39705 (July 10, 2008); *see also Assessment of the Third-Party Certification Pilot for Aquacultured Shrimp*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm265934.htm> (last updated Aug. 27, 2015).

212. Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. 45,782, 45,786 (proposed July 29, 2013) (to be codified at 21 C.F.R. pts. 1, 16).

213. David Acheson, *Third-Party Audits—Their Crucial Role in Moving Forward with FSMA and Food Safety*, FOOD SAFETY NEWS (Nov. 27, 2012), <http://www.foodsafetynews.com/2012/11/third-party-audits-their-crucial-role-in-moving-forward-with-fsma-and-food-safety/>.

The private auditors chosen in the enforcement program, discussed above, tended to visit firms more often, and may have combined inspection and advice, thereby increasing compliance.²¹⁴ In Canada and the United Kingdom, the use of private, retailer-driven farm assurance schemes has been shown to enhance food safety.²¹⁵ In a report submitted by McAllister and commissioned by the Administrative Conference of the United States, the author hailed third-party certification programs, stating that “third-party programs may be particularly effective when regulated products or processes are international in scope”—while also recognizing that these programs have the potential to undermine regulatory goals and impose high costs.²¹⁶ Using three companies as examples, the GFSI notes that suppliers with good food safety practices help increase reliability of supply, reduce costs for quality and procurement departments, reduce staff time on recalls and withdrawals, and increase customer loyalty—all of which lead to increased sales.²¹⁷

Gaining Industry Cooperation and Reducing the Regulatory Burden. The history of Internet regulation provides guiding principles for adopting a different regulatory structure to gain, or re-gain, industry cooperation, which can be translated for the purpose of revising food safety regulation. While current discussion on the future of the Internet focuses on whether or not regulating the Internet is prudent (e.g., network neutrality debates), one may recall that the Internet began as a government-backed operation and was privatized in the 1990s.²¹⁸ Policymakers realized that a new regulatory model was needed outside the traditional command-and-control model as corporative norms began to break down.²¹⁹ As options for the future of the Internet were emerging, telecommunications and technology law scholar Phil Weiser

214. Verbruggen & Havinga, *supra* note 11, at 21.

215. Martinez et al., *supra* note 178, at 304–06.

216. See ADMIN. CONFERENCE OF THE U.S., ADMINISTRATIVE CONFERENCE RECOMMENDATION 2012-7: AGENCY USE OF THIRD-PARTY PROGRAMS TO ASSESS REGULATORY COMPLIANCE (2012) (noting that in 2012, the Administrative Conference of the United States, an independent body that provides recommendations for federal agency procedures, recommended, based on a comprehensive report prepared by consultant Lesley McAllister, addressing some issues arising from agencies developing third-party programs); LESLEY K. MCALLISTER, THIRD-PARTY PROGRAMS TO ASSESS REGULATORY COMPLIANCE (2012), <https://www.acus.gov/sites/default/files/documents/Draft-Report-on-Third-Party-Programs-to-Assess-Regulatory-Compliance.pdf>.

217. See GFSI, GFSI GENERAL PRESENTATION (2015), http://www.mygfsi.com/files/Information_Kit/GFSI_GeneralPresentation_201511.pdf (citing food safety gains and cost reductions as a result of GFSI benchmarking).

218. Philip J. Weiser, *The Future of Internet Regulation*, 43 U.C. DAVIS L. REV. 529 (2009).

219. *Id.*

recommended that the FCC act as a co-regulator (granting decision-making power to a self-regulatory organization who operates under FCC oversight), while also acting as a norm entrepreneur (identifying areas of collaboration) and as an ex-post adjudicator of breakdowns in cooperation.

Third-party certification can reduce an industry's regulatory burden. In 2006, the FDA and Health Canada initiated the pilot "Multipurpose Audit Program."²²⁰ The pilot explored the potential benefits to medical device manufacturers and agencies of using a single third party to conduct both FDA and Health Canada inspections and audits at the same time in one joint audit-inspection. The hope was that, using one third-party to simultaneously meet FDA and Health Canada regulatory requirements for systems quality, could potentially reduce the industry's regulatory burden.²²¹ The results from the ten joint audit-inspections under the pilot showed that the joint approach reduced the time spent in manufacturing facilities by about one-third, on average, compared to the estimated time required for separate FDA and Health Canada audits and inspections—thereby reducing the regulatory burden for the industry.²²² In addition, the FDA and Health Canada gained a better understanding of their respective audit and inspection approaches, providing a foundation for leveraging inspection resources in the future.²²³

2. Perils

There are several downsides to experimenting with New Governance. Examples are drawn from country examples (the Netherlands, the United Kingdom, and Canada), as well as industry examples in the fields of finance, privacy law, and environmental law. This Subsection highlights the five most prominent perils associated with third-party certification: (1) conflict of interest and lack of independence, (2) overreliance on the "checklist" mentality, (3) auditor incompetence, (4) no requirement to disclose, and (5) mismanaging third-party certifiers.

Conflict of Interest and Lack of Independence. When private auditors are paid for by their auditees, a conflict arises between the financial interest of the auditor and protecting the public from food safety risks. This lack of independence prevents an objective audit—a problem that has been identified with third-party certification systems.²²⁴ In economic terms, auditors have a financial interest in getting hired and

220. See U.S. FOOD & DRUG ADMIN., *supra* note 3.

221. *Id.*

222. *Id.*

223. *Id.*

224. Hatanaka & Busch, *supra* note 107.

reired by suppliers, and as profit maximizers, suppliers naturally shop around for the cheapest certification they can obtain. The tension with this is that auditors also have a professional obligation to report food safety risks. Lytton and McAllister discuss incentives for private certifiers to acquire accounts from suppliers, who want the cheapest certification, thus leading to certifiers lowering their standards of inspection.²²⁵ The incentive is for a company to hire a certification body that provides the company with the best chance to become certified.²²⁶

In the financial sector, the problem of auditor independence stems from the auditor having two masters: the client and the shareholder.²²⁷ Third-party certifiers “are thus placed in an inherently difficult position, since they are in effect public fiduciaries employed by the very private actors whose activities they are supposed to assess and monitor.”²²⁸ In some situations, financial auditors and third-party certifiers are so eager to serve their clients that they may help their client find ways to formally comply with rules while achieving outcomes that the rules were intended to prevent. The problem of auditor independence in financial audits is exacerbated when auditing firms provide their clients with additional “non-audit” consulting and tax services.²²⁹ Demski’s Enron example summarizes the difficulties in using third-party certifiers

225. Lytton & McAllister, *supra* note 27.

226. Albersmeier et al., *supra* note 151.

227. See Amy Shapiro, *Who Pays the Auditor Calls the Tune?: Auditing Regulation and Clients’ Incentives*, 35 SETON HALL L. REV. 1029, 1031 (2005) (arguing that the auditor problem is a problem of two masters and that the law needs to be written “so that auditors recognize proper incentives and serve only one master, a master whose own interests are aligned with those of the investing public”). See generally Cary Coglianese & David Lazer, *Management-Based Regulation: Prescribing Private Management to Achieve Public Goals*, 37 LAW & SOC’Y REV. 691, 718 (2003) (concluding that management-based regulation needs to be designed in a way that ensures firms are monitored and requirements enforced, and more frequent inspections by government, independent third-party auditors, or committees that include union or community representatives will likely be critical to the success of management-based strategies).

228. Errol E. Meidinger, *The New Environmental Law: Forest Certification*, 10 BUFF. ENVTL. L.J. 211, 284 (2002).

229. Keith A. Houghton & Christine A. Jubb, *The Market for Financial Report Audits: Regulation of and Competition for Auditor Independence*, 25 LAW & POL’Y 299, 308–09 (2003); see, e.g., Patricia A. McCoy, *Realigning Auditors’ Incentives*, 35 CONN. L. REV. 989, 990 (2003) (stating that the basic problem afflicting the accounting industry is that “accounting firms work for the companies they audit”); Geoffrey P. Miller, *Catastrophic Financial Failures: Enron and More*, 89 CORNELL L. REV. 423, 423–25 (2004) (discussing questionable accounting and questionable accountants in recent catastrophic financial collapses); see also Jonathan Macey & Hillary A. Sale, *Observations on the Role of Commodification, Independence, and Governance in the Accounting Industry*, 48 VILL. L. REV. 1167, 1167 (2003) (finding that, over time, accounting firms began to market professional services beyond the audit and those services became more profitable than the audits).

in finance. He notes that independence is psychologically impossible because (1) accounting firms provide non-auditing services, such as consultation and tax; (2) personnel often move from accounting firms to their clients' firms; and (3) there is a close affinity with the client.²³⁰

In environmental law, one common complaint is that companies have the opportunity to shop around for a favorable verifier and put pressure on verifiers for a favorable outcome.²³¹ Using forestry as an example, Sasha Stashwick argues for true third-party certification—i.e., the Forest Stewardship Council or Roundtable on Sustainable Biofuels—which reliably provides standards and assessments, as well as public agreements between environmental advocates and corporations, over “self-certification”—i.e., the Sustainable Forestry Initiative—which lacks financial independence from the industry they claim to oversee and thereby allows for destructive forestry practices.²³²

Sustainable forestry initiatives have been criticized for having unbalanced representation and no real decision-making authority. The Programme for the Endorsement of Forest Certification Schemes, established by the forest and wood products industry (and which includes the Sustainable Forestry Initiative as a benchmarked scheme), fails to adequately comply with three minimum environmental requirements—the prohibition on natural forest conversion, the protection of key habitats and species, and the respect for indigenous peoples and local community rights—because it lacks a balanced representation and real decision-making authority due to its failure to include nongovernmental organizations and other stakeholders in its general assembly.²³³ In addition, the Programme does not require freely available information about the forest management practices and decisions. Finally, other noted problems with audits include: (1) small audit teams and too little time devoted to assessing performance, (2) poor standards enforcement, and (3) lack of oversight of the certifying

230. Joel S. Demski, *Corporate Conflicts of Interest*, 17 J. ECON. PERSP. 51, 56–57 (2003).

231. See Neil Gunningham, *Environmental Auditing: Who Audits the Auditors?*, ENVTL. & PLAN. L.J., Aug. 1993, at 229, 234 (assuming the existence of a market in verifier services, companies have the opportunity to shop around for a favorable verifier and put pressure on verifiers for a favorable outcome); see also McAllister, *supra* note 199.

232. Sasha Stashwick, *Foxes Guarding the Henhouse; Why “Self-Certification” in the Biomass Industry Threatens our Forests*, SWITCHBOARD NAT. RESOURCES DEF. COUNCIL STAFF BLOG (June 4, 2013), http://switchboard.nrdc.org/blogs/slyutse/the_fox_is_guarding_the_hen_ho.html. See generally Errol Meidinger, *The Administrative Law of Global Private-Public Regulation: The Case of Forestry*, 17 EUR. J. INT’L L. 47 (2006) (finding that while the certification programs are becoming increasingly transparent and participatory, some of them still need considerable improvement and all of them face serious challenges).

233. GREENPEACE ET AL., ON THE GROUND 2011: THE CONTROVERSIES OF PEFC AND SFI (2011).

bodies by the system itself.²³⁴

Overreliance on the “Checklist” Mentality. A great deal of trust goes into the process of certification—trust that may perhaps be unwarranted when certifiers over-rely upon “checklists” and thereby capture a “snapshot in time.” As a certification body auditor admits, “[w]e are only on a production site for 3 days out of 365. It is just a snapshot in time. The ultimate responsibility to mitigate unforeseen hazards or defects is on the producers and processors who are there 365 days, and not on us. We are just a checker.”²³⁵ In the 2009 Salmonella in peanuts outbreak, implicating contaminated peanuts manufactured by the Peanut Corporation of America (“PCA”), legal records showed that Salmonella had been present in PCA peanuts as early as 2007. To be sure, it is not possible for an auditor to check every aspect of a company’s methods, and most auditors rely on checklists, as well as reviewing the documentation that a company has on itself, to complete the audits. In the same way, some accreditation bodies accredit certification bodies based on documentation they have submitted.

Auditor Incompetence. Returning to the 2011 Colorado Listeria Outbreak, a deadly outbreak that was ultimately sourced to Colorado-based cantaloupe farmers: The farmers had received a nearly perfect rating during their audit, however, the Primus Labs auditor who was responsible for auditing the Colorado outfit was young and new to the job.²³⁶ This highlights the point that Doug Powell and others raise in the literature, that there have been many foodborne illness outbreaks linked to food processors that have passed third-party audits and inspections, raising questions about the utility of both.²³⁷ The authors identify limitations of food safety audits and inspections and provide recommendations for strengthening the system, based on developing a strong food safety culture throughout the food safety system.²³⁸ Auditor incompetence has been cited repeatedly in the PCA Salmonella outbreak, noted above.²³⁹ In the PCA case, the auditor was an expert in

234. *Id.*

235. Hatanaka & Busch, *supra* note 107, at 86.

236. See Lytton & McAllister, *supra* note 27; see also Michael Booth & Jennifer Brown, *Colorado Cantaloupe Farmers Charged by Federal Officials in Fatal Listeria Outbreak*, DENVER POST (Sept. 26, 2013), http://www.denverpost.com/breakingnews/ci_24182307/colorado-cantaloupe-farm-charged-by-federal-officials-fatal.

237. Douglas Powell et al., *Audits and Inspections Are Never Enough: A Critique to Enhance Food Safety*, 30 FOOD CONTROL 686 (2013).

238. See *id.* (recommending that including risk-based verification steps to the auditing system would increase the food safety culture).

239. See *id.* at 689 (noting that even employees said the facility was “a dump,” but did not report their concerns to officials before people became ill and died); see also Michael Moss &

fresh produce and not peanuts. With respect to auditor scope, there are instances where the audit did not include all of the ingredients. In the 2007 outbreak related to Salmonella in Pirate's Booty brand popcorn, the audit did not extend to the culprit, imported spice ingredients.²⁴⁰ Regulators should consider these examples related to auditor expertise and scope as they design improved auditor programs.

No Requirement to Disclose. The Netherlands Food and Consumer Product Safety Authority noted a problem with using private certifiers: systems, auditors, and inspectors are not required to advise and alert the agency of situations involving major noncompliance and serious risk to public health and safety. The Authority found that, without mandating the transmission of noncompliance to the agency, it is possible that firms may slip through the system.²⁴¹ In other words, when firms are not required to report breaches in food safety, those breaches, and their corresponding threats to health and safety, will persist.

Mismanaging Third-Party Certifiers. The growth of Internet-related business and the amount of personal data that is exchanged over the Internet has heightened consumer fears over Internet security and privacy. Companies have emerged to increase consumer trust by offering third-party certification programs such as the Trusted Download Program or the web seal program from TRUSTe, a major provider of privacy certifications for online businesses.²⁴² TRUSTe's

Andrew Martin, *Food Problems Elude Private Inspectors*, N.Y. TIMES (Mar. 5, 2009), http://www.nytimes.com/2009/03/06/business/06food.html?pagewanted=2&_r= (criticizing third-party audits using the PCA example). See generally Roy Costa, *Process and Substance in Third-Party Food Safety Audits*, FOOD SAFETY NEWS (Jul. 24, 2014), <http://www.foodsafetynews.com/2014/07/process-and-substance-in-third-party-food-safety-audits/> (arguing that weaknesses in third-party audits—no requirement to run scientific tests, advance notice of audits, buyers can stop audits, no requirement to report failures to the FDA or the public—will continue to cause food-borne illness outbreaks, citing the PCA salmonella outbreak and the Listeria outbreak from cantaloupes).

240. See Dan Flynn, *Veggie Booty Salmonella Outbreak*, FOOD SAFETY NEWS (Sept. 22, 2009), <http://www.foodsafetynews.com/2009/09/meaningful-outbreak-9-veggie-booty-salmonella-outbreak/> (reporting that the FDA inspection determined that the supplier of Veggie Booty's spices failed to inspect and handle raw materials to ascertain that they were clean and suitable for processing into food).

241. See Powell et al., *supra* note 237, at 689 (noting that third-party auditing can assist regulatory agencies, but only if the data is shared with agencies).

242. See Tom Spring, *The Trouble With Truste*, PCWORLD, <http://www.peworld.com/article/129338/article.html> (last visited Mar. 20, 2016); see also Pingjun Jiang et al., *How Third-Party Certification Programs Relate to Consumer Trust in Online Transactions: An Exploratory Study*, 25 PSYCHOL. & MARKETING 839 (2008) (stating key strategy to increase consumer trust in ordering has been participation in third-party certification programs); Trevor T. Moores & Gurpreet Dhillon, *Do Privacy Seals in E-Commerce Really Work?*, COMM. ACM, Dec. 2013, at 265 (finding three main privacy seals—TRUSTe, WebTrust, and BBBOnline—have adopted a set of data privacy principles to ensure compliance by recipient websites).

efforts to certify software programs as safe and in compliance with the group's privacy standards have been hailed as "innovative effort[s] to address a serious online consumer concern";²⁴³ however, independent audits have reported that sites claiming to be TRUSTe-compliant often are not and that some companies offering TRUSTe-approved programs have been criticized in the past for distributing adware, spyware, and attempting to make changes to system settings on personal computers. As recent as 2014, TRUSTe settled a lawsuit for deceiving consumers about its recertification program for the company's privacy practices, as well as perpetuating its misrepresentation as a non-profit entity.²⁴⁴ Important for this Article's purposes, TRUSTe failed to conduct annual recertification of companies holding TRUSTe privacy seals.²⁴⁵

The paragraphs within this Subsection reviewed the criticisms implicating third-party certification, drawing attention to examples in several industries. While there are certainly concerns that were not noted—for instance, that over-certification is encouraging confusion and stifling innovation throughout the entire system—these and other topics are ripe for future study but not discussed herein.²⁴⁶

III. RESISTING COMPLACENCY: A ROADMAP FOR IMPROVING THE U.S. RULES

Passing the FSMA, with its focus on prevention and New Governance features, was groundbreaking—but the work is not done. In a few years when the FSMA is finally implemented, the United States will, for the first time in history, begin using private third-party certifications to monitor imports. I have argued that the transition to use private parties to fulfill traditional government function of screening imports is a move toward New Governance and has the potential to raise food safety standards beyond minimum standards available with Codex. I have argued that we have limited options given financial constraints and international agreements, and that New Governance is the only way for the United States to raise food standards. And yet, the New Governance framework is not perfect. Regulators need to be

243. Spring, *supra* note 242 (quoting Lydia Parnes, director of the Consumer Protection Division with the Federal Trade Commission ("FTC")).

244. Press Release, FTC, TRUSTe Settles FTC Charges It Deceived Consumers Through Its Privacy Seal Program: Company Failed to Conduct Annual Recertifications, Facilitated Misrepresentation as Non-Profit (Nov. 17, 2014), <https://www.ftc.gov/news-events/press-releases/2014/11/truste-settles-ftc-charges-it-deceived-consumers-through-its>.

245. *Id.*

246. See Marc Stoiber, *Is Eco-certification a Carrot—or Killer—for Innovation?*, FAST CO. (Apr. 9, 2010, 7:04 PM), <http://www.fastcompany.com/1612295/is-eco-certification-a-carrot-or-killer-for-innovation> (noting that overabundance of labels encourages confusion).

mindful of case studies where New Governance has not been successful, in financial regulation,²⁴⁷ for instance, and in other fields.²⁴⁸ This final Part describes how moving to a New Governance system will address the identified pitfalls. It also suggests lingering concerns.

A. Regime Enforcement

For third-party certification to be successful, regulators need to be mindful of the pitfalls associated with implementing third-party certification, and of practical recommendations. Thus, this Section takes the perils noted in Part II—(1) conflict of interest and lack of independence, (2) overreliance on the checklist mentality, (3) auditor incompetence, (4) no requirement to disclose, and (5) mismanaging third-party certifiers—and evaluates how the FSMA addresses these issues by providing recommendations toward designing a successful third-party certification program.

Can we confidently assert that the New Governance paradigm will lead to higher food safety, as suggested? Potential solutions to each pitfall are discussed followed by how the FSMA specifically addresses the concern and where the FSMA falls short. In the case of the 2011 Colorado Listeria outbreak, for example, food safety regulators learned that auditor competence was an issue and a careful reading of the FSMA suggests that the rules address concerns with auditor competency in this case.

In some cases, more legislative authority or guidance is necessary. With respect to conflict of interest, third-party auditors are not prevented from working in-house for their clients and auditors are not prevented from performing other services for their auditees. The “checklist mentality” could be addressed by requiring a certain number of unannounced visits as is being considered by the GFSI. Auditors could achieve competence if they were required to complete certain defined coursework and field training instead of fulfilling recommendations. There are other cases where more legislative authority is not necessary. For instance, the FSMA rules are appropriate with respect to the requirement to disclose and management of third-party certifiers.

Conflict of Interest and Lack of Independence. The literature on

247. Cristie Ford provides caution for implementing a localized, privatized, horizontally-situated regulatory regime. Cristie Ford, *New Governance in the Teeth of Human Frailty: Lessons from Financial Regulation*, 2010 WIS. L. REV. 441.

248. It took ten years for the U.S. Federal Government to develop organic standards because public-private co-regulation and cooperation failed.

third-party certification and privatization generally teaches us that conflicts of interest arise when the auditor is paid by the entity being audited;²⁴⁹ the same literature explains that such conflicts are a structural feature of any private scheme. Conflicts of interest can be minimized by leveraging a network of actors who all play a role in constraining economic actors.²⁵⁰ Laura Dickinson's early work on privatization stresses the importance of requiring strong accountability mechanisms (through contracting) for private actors.²⁵¹ Lytton and McAllister's comprehensive study on third-party certification and conflict of interest recommends oversight mechanisms to address this problem, including: supplier self-regulation, audit firm quality control, buyer vigilance, tort litigation, liability insurance, accreditation, food safety scheme licensing, and benchmarking.²⁵² Some of these mechanisms certainly include contracting as Dickinson proposed. For auditors to certify against a scheme, they have to be licensed by a scheme owner, which means abiding by the scheme owner's conflict-of-interest rules. Food safety scheme licensing creates an incentive for auditors to conduct audits that meet the conflict-of-interest standards of scheme owners.²⁵³ The FSMA rules emulate those found in the private sector—the FDA approves accreditation bodies, which have conflict-of-interest rules that third-party certifiers will have to adopt.

Case studies also provide useful guidance. In the financial accounting literature, deficiencies in auditor independence have been attributed to the lack of a strong, governmentally sanctioned system of rules and standards to regulate the accreditation of auditors and the practice of auditing.²⁵⁴ And in the environmental (forestry) context, including nongovernmental organizations in the discussion has proven pivotal.²⁵⁵

The FSMA rules have guidelines on accrediting auditors and contain standards on audit firm quality control and accreditation as means to

249. See McAllister, *supra* note 199, at 28–44.

250. See Abraham L. Newman & David Zaring, *Regulatory Networks: Power, Legitimacy, and Compliance*, in INTERDISCIPLINARY PERSPECTIVES ON INTERNATIONAL LAW AND INTERNATIONAL RELATIONS: THE STATE OF THE ART 244 (Jeffrey L. Dunoff & Mark A. Pollack eds., 2013).

251. See Laura A. Dickinson, *Public Law Values in a Privatized World*, 31 YALE J. INT'L L. 383, 402 (2006) (setting forth ways in which government contractual provisions could be used to extend and enforce public law values in the foreign affairs privatization context).

252. See Lytton & McAllister, *supra* note 27, at 304 (table 1 presents an overview of oversight actors, regulatory instruments, and comparative criteria).

253. *Id.* at 319.

254. Shapiro, *supra* note 227, at 1056–64; see also Hatanaka & Busch, *supra* note 107.

255. See *supra* notes 231–233 and accompanying texts.

prevent conflicts of interest. The proposed FDA rules often cite International Standard Organization standard “ISO/IEC 17011:2004” on accreditation bodies²⁵⁶—a standard that private schemes use for their accreditation purposes. The FSMA contains conflict-of-interest rules for auditors,²⁵⁷ which give the FDA authority to closely monitor these systems and revoke an accreditation body’s recognition or withdraw an auditor’s accreditation for good cause—for example, if a supplier that it certifies is linked to a serious outbreak of foodborne illness; if it refuses to grant the FDA access to its records; if it demonstrates “bias or lack of objectivity”; or if its “performance call[s] into question the validity or reliability of its food safety audits.”²⁵⁸ To counter specific perils that were highlighted in the finance industry—such as the trend for personnel to often move from accounting firms to their client firms and the close affinity the accounting firms hold with the client²⁵⁹—the FSMA has been drafted with a “written program to protect against conflicts of interest.”²⁶⁰ The contents of the program propose to ensure that third-party auditors do not own or have an interest in an eligible entity to be certified or an affiliate of such an entity, and that a third-party auditor cannot accept gifts or payments of value from the eligible entity to be audited or certified.²⁶¹ One drawback is that this program is limited, however, as it does not prevent third-party auditors from working in-house for their clients.

The critique to include nongovernmental organizations in the regulatory conversation is not a foreseeable problem with respect to the FSMA. The FDA participates in and collaborates with seven leading

256. See INT’L ORG. FOR STANDARDIZATION, ISO/IEC 17011:2004: CONFORMITY ASSESSMENT—GENERAL REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING CONFORMITY ASSESSMENT BODIES (2004), http://www.iso.org/iso/catalogue_detail?csnumber=29332 (discussing the conformity assessment); see also *ISO/IEC Standard for “One-Stop Accreditation” to Boost Cross-Border Trade*, ISO (Nov. 15, 2004), http://www.iso.org/iso/home/news_index/news_archive/news.htm?refid=Ref941 (describing the conformity assessment).

257. See Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. 45,782, 45,802, 45,829 (proposed July 29, 2013) (to be codified at 21 C.F.R. pts. 1, 16) (proposed § 1.624 requires a recognized accreditation body to take certain steps to safeguard against conflicts of interest, including implementing a written conflict of interest program, while proposed § 1.624(c) requires the recognized accreditation body to make information on the timing of payments available on its website, creating transparency, thereby lending to the credibility of the program).

258. See *id.* at 45,819 (proposed § 1.664).

259. See Demski, *supra* note 230, at 56–57.

260. See U.S. FOOD & DRUG ADMIN., THIRD-PARTY AUDITOR/CERTIFICATION BODY ACCREDITATION FOR FOOD SAFETY AUDITS 12 (2015), <http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM455331.pdf>.

261. See *id.* at 14–15 (discussing proposed §§ 1.657(a)(1)–(a)(4)).

food safety nongovernmental organizations,²⁶² as well as with networks of regulators and nongovernmental public health organizations. Moreover, the FDA has held public meetings in which many of these organizations were present, thereby cutting against the argument that the FDA omits nongovernmental organization input.²⁶³ Other concerns drawn from the environmental context—audit teams and too little time were devoted to assessing performance, the poor standards enforcement, and a lack of oversight of the certifying bodies by the system itself²⁶⁴—are not addressed by the FSMA.²⁶⁵

The food industry also contains certain built-in safeguards to counter concerns that a lack of independence arises when auditing firms provide their clients with additional “non-audit” consulting and tax services.²⁶⁶ Unlike the finance sector, this problem is not nearly as severe with food certification. In fact, most GFSI-benchmarked schemes (e.g., SQF, PrimusGFS, Global Aquaculture Alliance, GlobalGAP, and IFS PACsecure) provide only auditing and certification services, in addition to some ancillary services to support those primary services. Some schemes provide only certification services (e.g., Global Aquaculture Alliance and IFS PACsecure), while other schemes provide certification services plus consulting to help clients achieve certification (e.g., SQF), or certification plus an “add-on” certification for workers’ health, safety, and welfare (e.g., GlobalGAP).²⁶⁷ There is one exception. The only scheme that provides a greater variety of services, suggesting the possibility of a conflict of interest, is PrimusGFS, which is owned by Azzule Systems.²⁶⁸ Azzule Systems provides data collection services

262. See *Food Safety*, *supra* note 141 (citing food safety nongovernmental organizations: the Association of Food and Drug Officials, the Association of Public Health Laboratories, the Council of State and Territorial Epidemiologists, the International Association of Food Protection, the International Food Protection Training Institute, and the National Environmental Health Association).

263. The FDA is a member of several of these organizations. The International Food Protection Training Institute was an FDA grant recipient in 2011. *Assisting the Integrated Food Safety System’s National Food/Feed Training Program*, GRANTS.GOV (July 12, 2011), <http://www.grants.gov/web/grants/view-opportunity.html?oppld=104573>.

264. See GREENPEACE ET AL., *supra* note 233.

265. See U.S. FOOD & DRUG ADMIN., *supra* note 260 (noting proposed § 1.642(a)(1)).

266. See Houghton & Jubb, *supra* note 229, at 308–09.

267. See, e.g., SQF INST., <http://www.sqfi.com> (last visited Mar. 20, 2016) (providing auditing and certification services and consulting to help clients (suppliers) achieve SQF); GLOBAL AQUACULTURE ALLIANCE, <http://gaalliance.org> (last visited Mar. 20, 2016) (providing “Best Aquaculture Practices Certification”); GLOBALG.A.P., http://www.globalgap.org/uk_en/ (last visited Mar. 20, 2016) (providing food safety certification and an “add-on” certification for workers’ health, safety, and welfare); PAC.CA, <http://www.pac.ca/pacsecure.html> (last visited Mar. 20, 2016) (providing only certification services).

268. PRIMUSGFS, <http://www.primusgfs.com> (last visited Mar. 20, 2016).

developed for laboratory data, quality assurance data, audit data, audit scheme management, document management, and supply chain management data. For this scheme, presumably if a supplier purchases certification services from PrimusGFS, other services provided by Azzule Systems may be at stake. Perhaps the FSMA rules could stipulate that auditors should not perform other outside services for their clients to avoid this concern.

Overreliance on the “Checklist” Mentality. There is a concern that auditors rely on “checklists” and “one-time visits.” The fear is that much could be missed—for instance, in the 2009 Salmonella in Peanuts outbreak, legal records show that Salmonella had been present in PCA peanuts as early as 2007. While Powell and others emphasize that instilling and enhancing a food safety culture is the most important thing companies can do, they do also note that:

Third-party audits are only one performance indicator and need to be supplemented with microbial testing, second-party audits of suppliers and the in-house capacity to meaningfully assess the results of audits and inspections. Any and all raw product suppliers should be included in the audit scope. More effective audit systems incorporate unannounced visits along with supplemental information into their framework²⁶⁹

How does the FSMA respond to these apparent problems? The FSMA rules on audit protocols contain some of these recommendations to rein in the “checklist mentality.” Particularly, the rules require that audit scope is provided in the auditor report.²⁷⁰ Further, the audit must include supplemental information outside the audit itself, such as “records . . . [the site’s] process(es), and the food that results from such process(es)[,] . . . environmental or product sampling and analysis,” and “any other activities necessary to establish compliance.”²⁷¹ Most importantly, the FSMA requires unannounced audits. An auditor is required to obtain a thirty-day operating schedule for the facility so that he can fulfill the statutory requirement to do unannounced audits.²⁷² The rule specifies how an unannounced audit must be conducted, “focus[ing] on the highest food safety risk(s) associated with the

269. Powell et al., *supra* note 237, at 689.

270. See Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. 45,782, 45812 (proposed July 29, 2013) (to be codified at 21 C.F.R. pts. 1, 16) (proposed § 1.652 requires audit scope, in line with ISO/IEC 17021:2011, clause 9.1.10.2).

271. *Id.* at 45,833 (proposed § 1.651(c)(2)).

272. *Id.* at 45,832 (proposed § 1.651(b)(1)). This is so the auditor can fulfill section 808(c)(5)(C)(i) of the Food Drug and Cosmetics Act “unannounced” food safety audits.

facility, its process(es), and food within the scope of the audit.”²⁷³

Evidence shows that the FDA considered several private standards in developing the audit protocols, including the unannounced audit protocol used by the British Retail Consortium, or BRC.²⁷⁴ In fact, the FSMA rules closely follow, but differ from, the BRC scheme policies for unannounced facility visits.²⁷⁵

Under the BRC scheme, an unannounced audit takes place only after a record of high scores on announced audits and may be conducted in two parts—first with a records review (planned visit) and then with a facility audit (unannounced visit). The BRC audit protocol allows for the unannounced audit to occur before a planned records review; however, the FDA will conduct an unannounced facility audit only after a planned visit. While it is possible that the FDA sequences the visits in this way to be able to attain information to conduct the site audit, it is possible that viewing the records may subconsciously influence the review. Another issue is that a thirty-day schedule of operations is provided—giving the audit team an opportunity to sufficiently plan the audit.

The FSMA rules do not require a certain number of adequate unannounced audits before audits can be announced or vice versa. GFSI has discussed this possibility, or alternatively, the option of at least defining a minimum number of unannounced audits in a given cycle.²⁷⁶ This could be something that all GFSI schemes are required to do in the future and something that the FSMA rules could implement in the future as well.

Auditor Incompetence. Previous outbreaks such as the one involving PCA peanuts have pointed to auditor incompetence as a prominent food safety regulation concern. In that case, the auditor was not qualified to audit peanut facilities. In the case of the 2011 Colorado Listeria outbreak, the auditor was young and inexperienced. How does the FSMA plan to address these shortcomings with third-party certification?

273. *Id.* at 45,833 (proposed § 1.651(c)(1)).

274. *See id.* at 45,788.

275. Press Release, SGS, Unannounced Audits: A Guide to the New BRC Requirements (Nov. 18, 2013), <http://www.sgs.com/en/Our-Company/News-and-Media-Center/News-and-Press-Releases/2013/11/Unannounced-Audits-A-Guide-to-the-New-BRC-Requirements.aspx> (noting the BRC Global Standard for Food Safety requires: “that a company achieved either a Grade A or B on its last audit, and opted for the [u]nannounced option [where the entire audit is conducted unannounced] within three months of their last certification). There is a second option for a partially unannounced audit where the Good Manufacturing Practice or factory processes audit is unannounced while the systems audit is conducted as a planned and arranged audit. *Id.*

276. *See* Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. at 45,833 (proposed § 1.651(c)(1)).

According to FSMA, “a third-party auditor can be a foreign government, an agency of a foreign government, a foreign cooperative, or any other third-party.”²⁷⁷ It must also meet standards for “legal authority, *competency*, capacity, conflicts of interest, quality assurance, and records” procedures.²⁷⁸ Before assigning an auditor to conduct a particular food safety audit, the agent must be deemed qualified to conduct the audit considering the scope and purpose of the audit and the type of facility, its processes, and type of food.²⁷⁹

Thus, the proposed FSMA rules contain standards to assure auditor competence, requiring further that the audit agent: has relevant knowledge and experience; participates in annual food safety training; does not have a conflict of interest; agrees to notify the accredited auditor or certification body of the discovery of “any condition that could cause or contribute to a serious risk to the public health”; and has not performed an audit on that facility in the last thirteen months (with some exceptions).²⁸⁰ Before assigning an auditor to conduct a particular food safety audit, the agent must be deemed qualified to conduct the audit considering the scope and purpose of the audit and the type of facility, its processes, and the type of food.²⁸¹ This mechanism directly addresses the PCA Salmonella outbreak where the auditor did not have an expertise in inspecting peanut operations.

Nonetheless, there are several downsides to the way in which the FSMA rules address auditor competence. While the FDA’s “Guidance for Industry” report provides details on these standards,²⁸² one critique of this guidance is that the document requires food safety experience but only provides “recommendations” (not requirements) on qualifications and training for auditors including coursework and field training.²⁸³ Another critique is that even though the FSMA third-party auditor requirements²⁸⁴ largely mirror those of GFSI,²⁸⁵ the standards found in

277. *Id.* at 45,807.

278. *Id.* (emphasis added); see also *Voluntary Third-Party Certification Programs for Foods and Feeds*, FDA, <http://www.fda.gov/regulatoryinformation/guidances/ucm125431.htm#VB> (last updated Jan. 25, 2016).

279. See Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. at 45,832 (proposed § 1.650(a-b)).

280. *Id.* (proposed § 1.650(a)(5)).

281. *Id.* (proposed § 1.650(a-b)).

282. See generally U.S. FOOD & DRUG ADMIN., *supra* note 260.

283. Powell et al., *supra* note 237, at 689.

284. See Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. at 45808.

285. GLOBAL FOOD SAFETY INITIATIVE, EXPLAINING THE GFSI AUDITOR COMPETENCE SCHEME 2 (2014), http://www.mygfsi.com/gfsifiles/information-kit/GFSI_Auditor_Competence_Workstream_Information_Package_ed1_August_2014.pdf (noting that the GFSI auditor

GFSI-benchmarked schemes are more rigorous. For instance, under GFSI-benchmarked schemes, a separate business entity registers food safety auditors based on knowledge examination and skills assessment, and manages an integrity program.²⁸⁶ A similar requirement is not found in the FSMA.

No Requirement to Disclose. One peril with not requiring firms to disclose food safety breaches immediately is that they will escape reprimand thereby compromising the food safety culture. The FSMA rules alter this. The FSMA rules stipulate that the auditor agree to immediately notify the accredited auditor or certification body of discovery of “any condition that could cause or contribute to a serious risk to the public health,”²⁸⁷ and in turn, the auditor or certification body must immediately notify the FDA of such condition.²⁸⁸

Mismanaging Third-Party Certifiers. In our earlier privacy example, TRUSTe had failed to conduct annual recertifications of companies holding TRUSTe privacy seals. The FSMA has a policy to require annual recertifications. According to the FSMA, recertification is required prior to expiration of its certification, and the FDA may require an eligible entity to renew a food certification at any time it determines appropriate.²⁸⁹ In addition, the FDA may, at any time, “conduct an onsite audit of an eligible entity that has received food or facility certification,”²⁹⁰ and if the certifier does not meet its responsibilities, the FDA can revoke its recognition.²⁹¹

B. Future Directions

In the future, the FDA will administer the FSMA and importers of FDA-regulated foods will have to attest that those foods comply with the FSMA rules. While some products will require third-party certification (e.g., high risk foods and producers belonging to the Voluntary Qualified Importer Program), for most suppliers, third-party certification will be voluntary. Certification will be provided by FDA-approved, third-party certifiers who are, in turn, certified by FDA-

competence scheme has four components: (1) competencies, (2) knowledge examination, (3) skills assessment, and (4) GFSI foundation—a business entity, separate and apart from GFSI, that will register food safety auditors based on knowledge examinations and skills assessment, register skills assessors, and manage an integrity program).

286. *See id.*

287. *See Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications*, 78 Fed. Reg. at 45,832 (proposed § 1.650(a)(5)).

288. *See id.* at 45,835 (proposed § 1.656(c)).

289. *Id.* at 45,821 (discussing proposed § 1.681(a–b)).

290. *Id.* at 45,838 (proposed § 1.680).

291. *Id.* at 45,804 (discussing proposed § 1.634).

approved accredited bodies.²⁹²

Although much remains uncertain, two trends provide a glimpse into what a New Governance paradigm for food safety may grow up to look like. First, as previously discussed, third-party certification has the potential to reduce an industry's regulatory burden. Part II.A discussed the opportunities related to third-party certification, and mentioned how third-party certification had the potential to reduce regulatory burden. Second, as noted earlier, in 2006, the FDA and Health Canada initiated the pilot Multipurpose Audit Program.²⁹³ The pilot explored the potential benefits to medical device manufacturers and the two agencies of using a single third party for audits and inspections to simultaneously meet FDA and Health Canada regulatory requirements for systems quality.²⁹⁴ The results showed that a joint approach eased the regulatory burden by reducing the time spent conducting separate FDA and Health Canada audits and inspections.²⁹⁵ In addition, the FDA and Health Canada gained a better understanding of their respective auditing and inspection approaches, providing a foundation for leveraging resources in the future.²⁹⁶

If one can foresee private third-party auditors conducting FDA and Health Canada inspections, one could foresee these auditors conducting FDA, Health Canada, and EU inspections, and so forth. This is similar to the way in which private third parties conduct inspections for the various GFSI-benchmarked schemes. In the end, the schemes are benchmarked: "once certified, accepted everywhere."²⁹⁷

Canada and the United States are negotiating similar food safety standards: accrediting the same accreditation bodies who will in turn certify third-party auditors to certify producers using the Canada standard or the U.S. standard in the same way that that GFSI-benchmarked schemes are interchanged today.

C. Addressing Legitimacy

The problem that private schemes lack international legitimacy in a global marketplace has been raised repeatedly. There are two principal

292. Sharon Mayl, Senior Advisor for Policy, Office of Foods & Veterinary Med., Addressing FSMA—Proposed Rules—Third Party Accreditation (Sept. 20, 2013), <http://www.fda.gov/downloads/InternationalPrograms/NewsEvents/UCM392450.pdf>.

293. See U.S. FOOD & DRUG ADMIN., *supra* note 3, at 25.

294. *Id.*

295. *Id.*

296. *Id.*

297. *What is GFSI*, GFSI, <http://www.mygfsi.com/about-us/about-gfsi/what-is-gfsi.html> (last visited Mar. 20, 2016).

arguments—the first centers on the WTO rules themselves and the second focuses on the “essence” of the WTO rules.

First, GFSI schemes and other private food safety schemes are criticized for creating unjustified and unnecessary barriers to international trade, particularly for developing countries.²⁹⁸ The issue of private standards was raised by St. Vincent and the Grenadines in 2005 when they opposed the operation of the EureGAP scheme used by supermarkets in the United Kingdom. Concerned about the negative impact on its banana exports of EureGAP standards for pesticides, St. Vincent and the Grenadines raised a “specific trade concern” in the WTO on this issue and the SPS Committee issued reports in 2007 and 2008.²⁹⁹ The European Union, following a prevailing sentiment shared by developing countries on the issue, denied WTO applicability beyond public standards. It rejected the complaint by stating that it was only about a private standard required by a private retailer and did not concern any official requirement of the European Union.

And yet, developing countries have a valid argument, despite the fact that private standards were developed *after* the negotiation of WTO agreements. The SPS Agreement applies to “all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade.”³⁰⁰ A threshold issue is whether this definition includes only government actions and whether it excludes measures imposed by private standards or by the private sector. Beyond this, Article 13 states: “Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories . . . comply with the relevant provisions of this Agreement.”³⁰¹ Developing countries interpret this Article as applicable to private standards. From this, it appears that the

298. See Comm. on Sanitary & Phytosanitary Measures, *Report by the Commonwealth of the Bahamas to the WTO-SPS Committee on Private Standards and the SPS Agreement: The Bahamas Experience*, WTO Doc. G/SPS/GEN/764 (Feb. 28, 2007) [hereinafter *Bahamas Report*]; Comm. on Sanitary & Phytosanitary Measures, *Private Industry Standards: Communication from Saint Vincent and the Grenadines*, WTO Doc. G/SPS/GEN/766 (Feb. 28, 2007); United Nations Conference on Trade and Development, *Trade and Development Report, 2007*, at iii, U.N. Doc. UNCTAD/TDR/2007 (Sept. 5, 2007); United Nations Conference on Trade and Development, *Food Safety and Environmental Requirements in Export Markets—Friend or Foe for Producers of Fruit and Vegetables in Asian Developing Countries?*, U.N. Doc. UNCTAD/DITC/TED/2006/8 (2007).

299. See *Private Standards*, *supra* note 22; see also Comm. on Sanitary & Phytosanitary Measures, *Considerations Relevant to Private Standards in the Field of Animal Health, Food Safety and Animal Welfare, Submission by the World Organization for Animal Health (OIE)*, WTO Doc. G/SPS/GEN/822 (Feb. 25, 2008) [hereinafter *Animal Health*].

300. SPS Agreement, *supra* note 17, at art. 1.

301. *Id.* at art. 13.

relationship between Article 13 and private standard-setting bodies hinges upon the definition of “non-governmental entities,” a term not defined in the SPS Agreement. Here, I simply identify the current debate and suggest that the distinction between private standard-setting body and nongovernmental entity is ripe for future investigation.

The second argument focuses on the “essence” of WTO law. The WTO and others have said that private standards are based on a “non-scientific, zero-risk, marketing approach” and would therefore contravene international trade rules (in theory).³⁰² In addition, private schemes are criticized for prescribing production and processing methods that are inappropriate and insensitive to local economic, social, religious, and cultural contexts, and stand against what states committed to under WTO membership.³⁰³ Finally, the private standard-setting procedures have been criticized for lacking transparency, being undemocratic, and for violating notions of fairness.³⁰⁴

With growing use of private standards, legitimacy is a real concern. While a solution to legitimacy rests outside the focus of this Article, Mark Suchman’s theory based on pragmatic, moral, and cognitive legitimacy, and Christine Parker and John Braithwaite’s thoughts on the significance of maintaining legitimacy could be used to ground legitimacy arguments on several descriptive foundations.³⁰⁵ In terms of specific steps, with respect to co-regulation in the Internet law context, Weiser promotes strengthening co-regulatory legitimacy through government oversight, using an established co-regulator, drawing upon expertise in that community, and operating in a transparent, effective, timely, and fair manner.³⁰⁶

CONCLUSION

This Article shows how, in an era with growing international commitments, traditional command-and-control regulation does not provide countries with the regulatory space to raise food safety standards. Countries are turning to New Governance approaches as the

302. *Animal Health*, *supra* note 299; *see also Bahamas Report*, *supra* note 298.

303. *See Animal Health*, *supra* note 299; *see also Bahamas Report*, *supra* note 298.

304. Hugh Campbell, *The Rise and Rise of EurepGAP: European (Re)Invention of Colonial Food Relations?*, 13 INT’L J. SOC. FOOD & AGRIC. 1 (2005); *see also* Holcomb et al., *supra* note 111 (noting that Wal-Mart announced corporate-wide efforts to have fresh produce suppliers follow the Produce Traceability Initiative protocol instituting a “100% money back” guarantee on freshness by 2014, with exemptions for small farms).

305. Parker & Braithwaite, *supra* note 142; Mark C. Suchman, *Managing Legitimacy: Strategic and Institutional Approaches*, 20 ACAD. MGMT. REV. 571 (1995).

306. *See* Weiser, *supra* note 218.

only way to raise food safety standards. This Article addresses this tension and challenges command-and-control regulation and traditional global governance in the food safety arena, and goes beyond that to provide a glimpse into a future for food safety governance. According to the FDA, it plans to “allocate agency resources based on risk, leveraging the combined efforts of government, industry, and public-and private-sector third parties.”³⁰⁷ The future, I suggest, is for countries to (1) raise food safety standards by borrowing the practice of using third-party certification from private standards (admittedly, controversial within the WTO), such as GFSI-benchmarked schemes, to expand public-private partnerships, while (2) continuing to pursue bilateral system recognition agreements (sanctioned by the WTO). These two avenues have the potential to raise food safety standards from the baseline to “SPS-plus” or to “SPS-plus *plus*” levels. Ultimately, by pursuing these two avenues, we could collaborate further, on a country-by-country basis, to share certification resources. As noted earlier, pilot studies have revealed efficiencies from using a single third party for audits and inspections to simultaneously meet U.S. (FDA) and Canadian (Health Canada) regulatory requirements for systems quality.

And yet, even if the United States were to adopt New Governance features, the benefits of adopting New Governance also come with potential pitfalls, both in terms of implementation and with respect to legitimacy. For instance, with respect to the conflict-of-interest concern, third-party auditors are not barred from working in-house for their clients, and auditors are not prevented from performing other services for their auditees. Nonetheless, I suggest that these concerns, and others, could be addressed with more legislative authority or guidance. The “checklist mentality” could be addressed by requiring a certain number of unannounced visits as is being considered by GFSI. Auditors could achieve competence if they were required to complete certain defined coursework and field training instead of fulfilling recommendations.

Practically speaking, many of the implementation issues can find remedies in legislative authority and guidance. The larger concern, however, beyond remedying the common shortcomings of New Governance, is legitimacy. While remaining beyond the scope of this Article, the use of private standards is controversial among many who

307. U.S. FOOD & DRUG ADMIN., PATHWAY TO GLOBAL PRODUCT SAFETY AND QUALITY 4 (2011), <http://www.fda.gov/downloads/aboutfda/centersoffices/officeofglobalregulatoryoperation/sandpolicy/globalproductpathway/ucm262528.pdf>.

feel that country use of private standards undermines the tenants and values of WTO membership. Without legitimacy, it is possible that countries will remain at the SPS-*default* or SPS-*plus* food safety standards levels and may be unable to reach the “top shelf,” the SPS-*plus plus* standard.