PUBLIC AND PRIVATE REGULATION - THE FOOD SAFETY MODERNIZATION ACT AND THE GOVERNANCE OF FOOD SAFETY IN THE UNITED STATES

By

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ABSTRACT

PUBLIC AND PRIVATE REGULATION - THE FOOD SAFETY MODERNIZATION ACT AND THE GOVERNANCE OF FOOD SAFETY IN THE UNITED STATES

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Using the Food Safety Modernization Act (FSMA) as a case study, the dissertation examines evolving patterns of governance in the contemporary agrifood system. Scholars today note that governing is carried out through patterns of *governance*, in which rules are set, applied and enforced by all manner of social-political actors nested in overlapping networks at multiple scales and across diverse geographies. The research explores who is participating in these networks, how the actors and networks are interacting, and the consequences these overlapping networks have for different sectors of society to meaningfully affect the choices about their lives.

The research examines how interactions among industry, public and private regulators, consumer groups and alternative agrifood activists in private and public-private regulatory networks shaped the policy choices in the FSMA and re-contoured the roles and relationships among public and private regulatory actors. The dynamics of proliferating policy networks are complicating the regulatory tasks of public regulators and undermining the capacity of some stakeholders to meaningfully participate in all of the relevant governance activities. In the enactment and rulemaking, alternative agrifood systems advocates sought to contest current agrifood governance patterns. They had some meaningful success establishing themselves as a distinct and legitimate interest group with potential political power. But ultimately governance continues to be dominated by corporate interests and neoliberal thinking. The conclusion is that emerging governance patterns are undermining traditional democratic normative values. Attempting to dramatically restructure the system seems untenable, while staying the course and perhaps re-conceptualizing normative values of governance is dissatisfying.

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Introduction

There is a movement among consumers to feel connected to the people, places, plants and animals that provide their food. They want to believe the food they consume comes from a system that does not destructively exploit people and land, and is nested in robust local, regional, national, and international systems that are resilient to ecological, economic, social and technological crises. They want everyone around the world to be able to access food that fulfills these normative values. And, of course, it needs to be healthy and delicious as defined by individuals' social and cultural values. Material realities make this unrealistic. Taking Michigan as an example, the summer bounty only lasts a few short months, and there are another few solid months where the only locally grown products available are winter greens, storable crops like carrots, tubers, cabbage, and apples, perhaps some beans and grains, and cured, pickled, frozen or otherwise preserved foods. This makes it difficult to achieve an interesting and healthy diet throughout the year.

Consumers could move to more temperate climates such as the foodie mecca of California. But this produces population pressures that compete with essential resources for food production, including land and, in the case of California, water.

Wanting a more diverse diet than local foods can provide, many turn to regional, national, and global food systems to procure food. As they do so, political and economic obstacles make it increasingly difficult to know where the food comes from, under what conditions it was produced and what kind of exploitation and harm occurred to get it to the consumer. But one can bet that, somewhere along the way, someone or something suffered more than one might want to know. Dissatisfied with these choices, people are joining movements for food sovereignty, community food security, food safety, food justice, organics, fair trade, and local food, among others. These movements share deep concerns about problematic outcomes being produced by an industrialized, globalized food system that is dominated by multi-national corporations. They all constitute efforts

to reform agri-food systems to produce greater justice and sustainability than is seen in today's systems of production and consumption.

The research for this dissertation was motivated by a common challenge for all these movements. Achieving the change they envision necessitates examining what laws and policies are currently in place, what their consequences are, what needs to be changed, and how can that change be achieved? These are questions about the rules of the game, and how the rules create winners and losers.

The task of answering these questions is more complicated than just examining U.S. governmental policy. Scholars today note that governing is carried out through patterns of *governance*, in which rules are set, applied and enforced by all manner of social-political actors nested in overlapping networks at multiple scales and across diverse geographies. There is not just one game in town. There is a whole proliferation of games, each with its own set of rules. In any given game, some players are on the field while others are sidelined, and the rules of the game are potentially under constant renegotiation.

Effecting change requires examining the causes and consequences of governing through the multiple, overlapping, nested networks that constitute contemporary governance. Doing so can help identify effective leverage points and provide better understanding of why past efforts have produced disappointing results.

The enactment and rulemaking of the Food Safety Modernization Act provides a useful case study for examining evolving agrifood governance patterns in the United States. To do this, there are three papers answering three research questions which each address different areas of concern of the governance literatures. These questions are:

- What factors shaped the substantive outcomes in the Food Safety Modernization act and to what extent and in what ways do these outcomes restructure the regulatory roles of state and non-state actors?

- To what extent and in what ways are the various regulatory networks reshaping the transparency, inclusiveness and accountability of governance processes?
- To what extent and in what ways does enactment and implementation of the FSMA restructure relations and powers of actors in the agrifood system?

This introduction proceeds in three steps. Section I provides an overview of the bodies of scholarship concerning governance relevant to food safety. Section II provides an orientation to the history of food safety regulation in the United States and explains why the FSMA is a productive case study for an interdisciplinary study of governance. Section III provides a brief overview of the three papers. Section IV concludes by foreshadowing how the findings and scholarship can be synthesized to provide a richer understanding of contemporary agrifood governance.

I. Governance Scholarship

A number of areas of scholarship are concerned with governance, or the "setting of rules, the application of rules, and the enforcement of rules" (Kjaer, 2004, p. 10). One governance scholar says "governance of and in modern societies is a mix of all kinds of governing efforts by all manner of social-political actors, public as well private; occurring between them at different levels, in different governance modes and orders….governing issues generally are not just public or private, they are frequently shared, and governing activity at all levels (from local to supra-national) is becoming diffused over various societal actors whose relationships with each other are constantly changing" (Kooiman, 2003). The focus of this study is on who these social-political actors are and how they are interacting with one another to set, apply and enforce rules to govern the U.S. agrifood system. The questions concern how the proliferation of regulatory networks and the actors' interactions within and between these networks are restructuring food safety governance in the U.S.

The boundaries between the various areas of scholarship are indistinct. However, they can loosely be grouped into governance scholarship emerging from political science and administrative law and agrifood governance studies emerging from sociology and geography.

The first broad area of governance scholarship is rooted in political science and integrates regulation and governance studies and administrative law. It is primarily concerned with understanding what and how choices about the institutions of governance are being made and the subsequent consequences for the regulatory roles and capacities of different sectors of society. From political science, a theoretical framework of policy networks was modified to provide a heuristic for simplifying the morass of actors and institutions involved in food safety governance in the U.S. Regulation and governance studies is an interdisciplinary field concerned with how public, public-private, and private institutions establish and enforce rules for controlling behavior of actors in networks in the regulated system. This literature draws attention to the importance of examining non-state regulatory activities that are accompanying globalization and restructuring governance relations. Closely related, administrative law analyzes what roles and procedures to assign to government regulators in the increasingly complex and dynamic environment of contemporary society. Thus, these literatures are concerned with understanding how regulatory institutions have been and should be designed to deal with increasingly globalized, complex networks of social-political actors engaged in setting, applying and enforcing rules.

The second broad area of scholarship is agrifood governance studies, which is rooted in sociology and geography. This scholarship has been concerned with understanding the social processes that are driving the globalization of agrifood supply chains and the privatization of governance processes, particularly the rise of regimes of private standards and third party audits. Agrifood governance studies are also deeply concerned with the distribution of power in contemporary governance patterns, the impacts of power distributions, whether and to what extent these power dynamics can be changed, and if so, how. Underlying many of the processes of globalization and

privatization has been an ideological preference for neoliberal governance, which denigrates government regulation and promotes governance through market mechanisms. This literature often highlights how ideologies of neoliberalism pervade institutional design choices and political contestation efforts.

This is a broad-stroke division and grouping of governance scholarship, which obscures how interdisciplinary the scholarship is. It should be noted that scholars and scholarly questions frequently transcend the divisions laid out here. Both are generally concerned with the distribution of political power and economic wealth. They also share a common interest in the emergence of private regulatory networks and the changing regulatory roles and capacities of state and non-state actors. However, they tend to examine the changes with slightly distinct lenses. As I see it, the first area focuses on describing institutional design options for the regulation and governance of society and understanding what choices are being made. The second area focuses on understanding the social processes that are underlying those institutional choices and the consequences those choices are having on food and agricultural production and consumption in different sectors of society. Through an examination of the FSMA and related food safety networks, these literatures' differing perspectives are combined to deepen understanding of the changing regulatory roles and capacities of state and non-state actors. Three research questions are combined to do this. (1) What factors shaped the substantive outcomes in the Food Safety Modernization act and to what extent and in what ways do these outcomes restructure the regulatory roles of state and non-state actors? (2) To what extent and in what ways are the various regulatory networks reshaping the transparency, inclusiveness and accountability of governance processes? (3) To what extent and in what ways does enactment and implementation of FSMA restructure relations and powers of actors in the agrifood system? Before turning to an overview of how these questions are answered, a brief overview of the history of US food safety regulation is in order to provide context for why the FSMA represents a fruitful case study for examining these issues.

II. Food Safety Regulation in the United States

The following history of US food safety regulation is taken from Barkan, 1985, Hutt & Hutt, 1984, and Merrill & Francer, 2000 and the FDA's history of itself on its website. For more complete discussions of provisions in the FSMA than provided below, see Eads & Zwagerman, 2011, Fortin, 2011, Hass, 2013, and Strauss, 2011. For an alternative perspective that is more narrowly focused on how political institutions are shaping the regulatory capacities of federal regulators, see Thomas, 2014.

History of Food Safety Regulation and Outbreaks

Origins of Regulation

In the United States, Federal regulation of food safety began in the late 1880's, with statutes prohibiting importation of adulterated tea and regulating production of oleomargarine (to protect the economic interests of the dairy industry). Local regulation began in the colonies, with a focus on ensuring quality for export, and state regulation of food safety aimed at addressing concerns proliferated throughout the 19th century. The 1890's saw the beginning of federal movement towards more comprehensive legislation, with the enactment of meat inspection laws meant to protect meat exporters from discrimination by foreign governments.

1906 – The First Comprehensive Federal Regulation

Truly comprehensive federal regulation of food safety began in 1906, with the enactment of the Pure Food and Drug Act and the Meat Inspection Act, which assigned food safety responsibilities to two separate agencies within the USDA.

Interestingly, the 1906 acts followed a nearly thirty year battle over federal regulation, within an economic and political context that was similar to today. The food and meat industries had been experiencing significant concentration as companies restructured to serve national, urbanized markets. Accompanying these changes, emerging stories about fraud and adulteration eroded

consumer trust in the depersonalized food manufacturers. The implementation of the legislation was preceded by strategic efforts by producers to develop certification schemes that would shore up consumer trust in the products; as those efforts failed, industry began to recognize the need for national legislation and moved to work with regulatory officials to develop mutually agreeable legislation and to prepare their businesses for the economic costs of the regulations (Barkan, 1985). Likewise, the FSMA was enacted following a drawn out effort by an increasingly concentrated industry to self-regulate in lieu of government action. Change did not occur until industry, recognizing it was facing recurring food safety crises and losing consumers to 'local' food, allied with the FDA and consumer organizations to support enactment of a comprehensive overhaul.

1938 & 1940 – Creation of the FDA's Role in the 20th Century

The next significant revision to US food safety laws occurred with the enactment of the Food, Drug and Cosmetic Act, which expanded FDA's authority to establish standards for the identity of foods, inspect facilities, and regulate labeling of products. Until the enactment of the FSMA, this was the most significant revision of the FDA's authorities.

In 1940, the FDA was removed from the USDA because of perceptions of a conflict of interest between the FDA's consumer protection role and the USDA's agriculture promotion role. Regulation of meat and poultry, however, remained with the USDA.

Today, food safety in the United States is mostly divided between two federal agencies, with the Food and Drug Administration having primary authority over all foods, except meat, poultry, and egg products which fall to USDA oversight. Numerous other federal agencies exercise overlapping authorities, including the EPA regulation of pesticide residues, the ATF oversight of alcohol, and CDC detection and investigation of food borne illnesses. In addition, every state also operates concurrent food safety programs, many of which are deputized on behalf of the FDA and USDA to conduct inspections and oversight.

Food Safety Crises Leading up to the FSMA

In 2010, Congress initiated a sweeping overhaul of agency authority and responsibility with enactment of the Food Safety Modernization Act. The enactment of the FSMA followed a series of high-profile food safety outbreaks associated with seemingly benign and healthful foods, including spinach, peanut butter, and jalapenos. Although concerns over microbial contamination of food first surfaced in the early 90's, with the E. coli outbreak from contaminated meat sold at Jack in the Box restaurants, these outbreaks highlighted that microbial contamination was, in fact, potentially a significant problem in fresh produce and any other products that might be consumed without final consumer cooking. At close to the same time, an incident of melamine contaminated animal feed from China highlighted FDA's intermittent and weak inspection of ever increasing food imports. Combined, these events led to a consensus among public, industry, and legislators that current regulation was not adequately protecting the U.S. food supply and something needed to be done.

The FSMA as a Sweeping Overhaul of FDA Authority

The FSMA aims to make three significant changes to FDA authority: FDA is required to develop a risk and science based preventive food safety system; FDA inspection, compliance, and recall authority are enhanced; and FDA is authorized to increase oversight of importers and their foreign suppliers through an audit and certification scheme. For purposes of this dissertation, the significant regulatory changes to focus on are the mandated preventive controls, FDA's expanded recall authority, and the imports controls programs.

Prevention

As part of their expanded preventive efforts, FDA is required to develop Hazard Analysis and Risk Based Preventive Controls (HARPC) for food processing facilities and standards for the growing and handling of fresh produce. HARPC is similar to the Hazard Analysis and Critical Control Point (HACCP) programs, except that it requires identification and control of a broad range of hazards, not just critical control points.

The standards for growing and handling fresh produce are a significant new authority for FDA. The law requires rules to be sufficiently flexible to be applicable to various types of entities growing different types of fresh produce and calls for the FDA to prioritize the implementation based on the known risks in raw agricultural commodities.

Enhanced Enforcement

Under the FSMA, FDA has been given drastically expanded authority to mandate increased records for high risk facilities, withdraw facilities' registrations to effectively shut down a plant, and mandate recalls in the event of an outbreak. Previously, the agency had no power to force companies to stop production and could only request that companies issue recalls (which companies largely did) or had to request a court order that would have the same effective result.

Imports

The final significant component of the legislation concerns imports. The law requires importers to verify that their suppliers are in compliance with the US's food safety system and mandates the FDA to develop a system for requiring third-party certifications for high-risk foods, fast-tracking importation for foods from voluntarily qualified importers, and recognizing certifications from foreign suppliers for purposes of fast-tracking. Since the FDA could not put inspectors in every foreign country that supplies food to the United States, instead it relies on certifications that come from third parties and foreign governments who can demonstrate that their inspection processes and qualifications meet FDA's standards.

The FSMA Case Study

The FSMA and overlapping policy networks were chosen for a case study because the law is a significant juncture in food safety governance. It was a major revision to the U.S. federal food safety regulatory system, setting the U.S. further down the path of co-regulation with private regulatory networks. The actual contests and outcomes in the law reveal potentially meaningful dynamics in the restructuring of power relations between state, industry and civil society actors. What has happened as efforts at federal legislation encounter private regulatory networks offers an

opportunity for examining the ongoing restructuring of roles and capacities of public and private actors to act as regulators. The overlap between federal regulation and related food safety regulatory networks allows examination of the consequences of the interplay between multiple, overlapping regulatory networks.

Struggles over food safety governance have been playing out prominently since the early nineties, when E. coli 0157:H7 outbreaks drew public attention to potential safety concerns in the US food supply. The enactment of the FSMA involved an interesting arrangement of actors. The law was partly driven by a corporate and consumer group alliance to address these concerns, and so in many ways serves the interests of corporate agrifood businesses and replicates their governance regimes. However, enactment and rulemaking have been beset with conflicts over the potential impacts on small and sustainable agrifood systems. Alternative agrifood advocates have accomplished some significant wins in these battles. And so it offers a valuable focal point for examining the evolving relationships and distribution of power among actors in the agrifood system.

The FSMA is also a useful focal point for studying how globalization and governance dynamics are changing the regulatory roles and capacities of public and private actors. When the FSMA was enacted, it was heralded as a sweeping transformation of the US food safety system. To the extent that it expands the FDA's mandate to implement preventative (rather than reactive) regulations and increases the FDA's enforcement authorities, it is a significant change. However, the law also builds heavily on private sector and industry-driven regulatory practices that are already used to govern far-flung supply chains, including HACCP-like standards for food manufacturing, standards for production and handling of fresh fruits and vegetables, and a system that relies on importers and accredited private and government auditors to oversee the safety of imported foods. The extent to which the law replicates, conflicts with, and relies on these overlapping regulatory regimes can

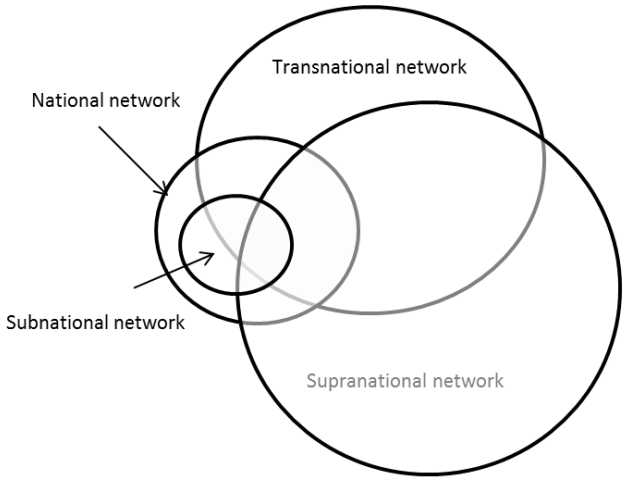
offer insights on how globalization and the emergence of networked-governance are restructuring the roles and capacities of public and private regulators.

The Study Framework

The study was conceptualized to understand how overlapping, interactive governance networks shape actors' participation in governance and the subsequent policy outcomes and impacts.

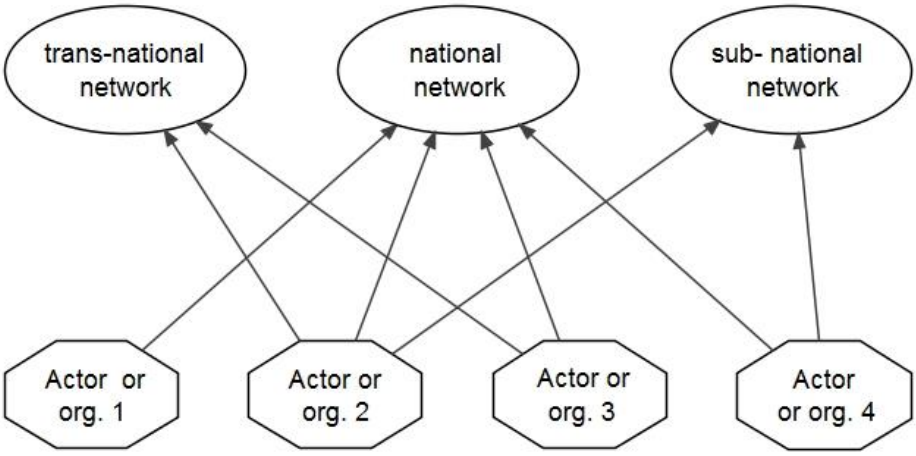
A simplified rendition of the overlaps between networks might look like this:

Figure 1: Overlapping Networks



Keeping in mind that the networks overlap, actors' participation in these networks might be graphically represented like this:

Figure 2: Actors' Participation in Governance Networks



To conceptually organize how actors and networks are interacting, the framework for the study was creating by modifying Marsh and Smith's model of policy networks (Marsh & Smith, 2000). As originally conceptualized, the framework is meant to capture the numerous variables that interact to produce policy change and outcomes in a traditional government policy setting. Marsh and Smith argue:

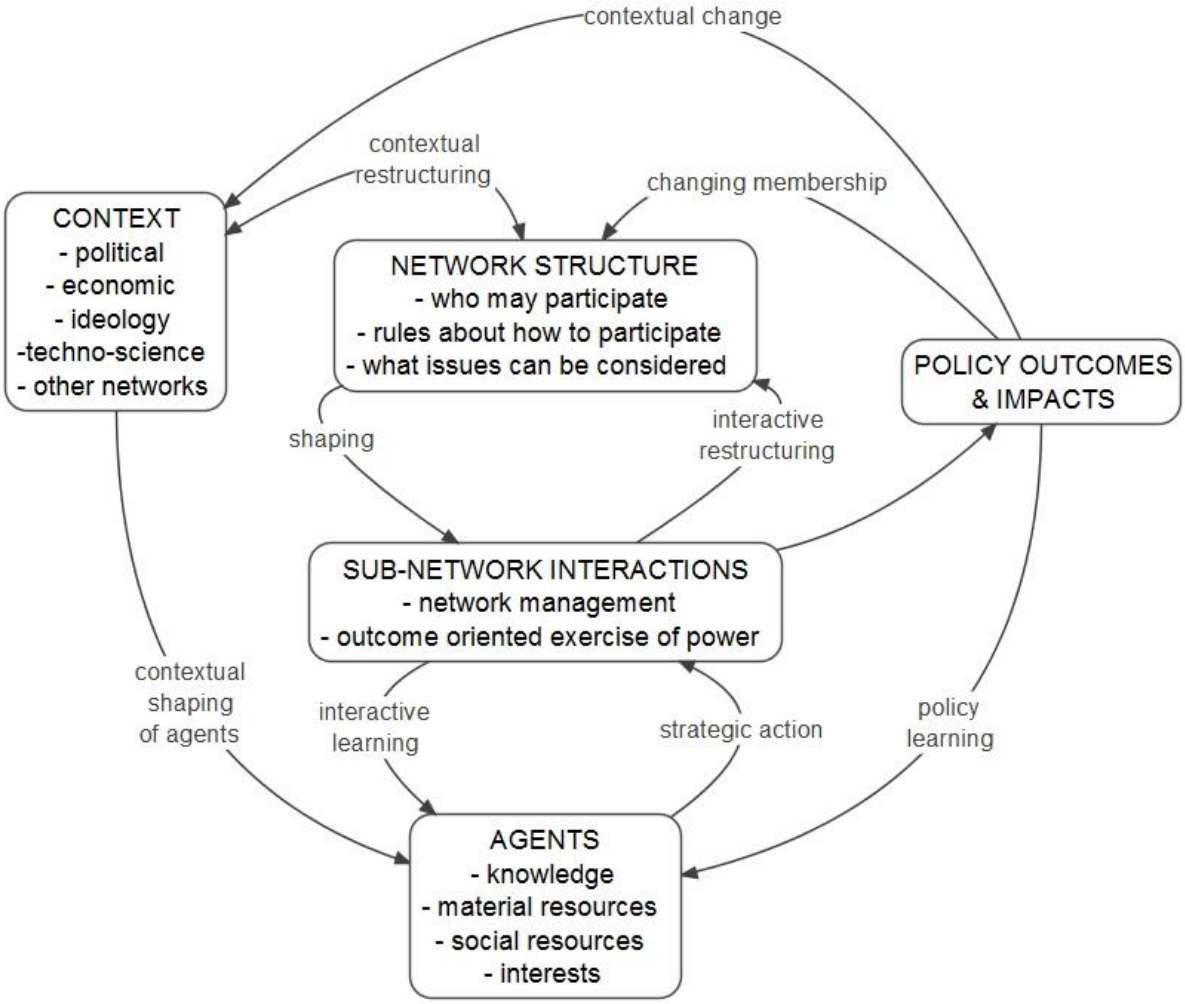
1. Models need to move beyond structures versus agency - networks can structure and constrain actor agency, but actor agency does matter and can itself restructure the networks.
2. Models need to move beyond network versus context – policy networks are structured and affected by their context, but they are capable of mediating how exogenous change affects internal dynamics; networks are also capable of affecting other networks.
3. Models need to move beyond networks versus outcomes – much of the literature concentrates on how networks affect policy outcomes, but research needs to also recognize that past outcomes can affect structures of the networks and actors' behavior within the network.

Their conceptual model is modified below, to add the argument that:

4. Governance occurs in multiple, overlapping networks that exist and interact at multiple levels. Models need to move beyond examining just government policy networks and enable study of the overlaps and interactions between networks as well as within networks.

Thus, the following graphical depiction is meant to explain how five categories of variables might interact within any given subnational, national, supranational, or transnational network. Supranational as used here refers to intergovernmental organizations that coordinate government activities from a level above national governments; transnational networks refer to networks of government and non-government actors that operate across national boundaries. These are context, the network structure, network interactions, the particular agents who are active in the given network, and previous and subsequent policy outcomes and impacts. An important component to note is that other networks are treated as part of the context of a network, in order to incorporate the concept of networks interactions. For any given network, the actors' traits which shape their interactions within the network can be expected to have been contoured by their experiences in other networks. These variables should be understood to be continuously interactively affecting one another.

Figure 3: Frameworks of Interactions Within and Between Governance Networks



Design and Methods

The research design explores actors' characterization of the structure and processes of these regulatory networks. The primary data for the research came from 37 semi-structured interviews with staff in industry and civil society organizations, federal and state regulators, congressional staff, food safety and regulatory compliance lawyers and academics, which were conducted between November 2013 and September 2014. The research was approved as exempt by the Institutional Review Board, IRB#13-793.

Initial interviewees were identified based on preliminary research of who the major participants were in the enactment and implementation of the law. Further interviewees were identified and contacted through attending industry and consumer food policy conferences, which were also used as observational opportunities for better understanding the issues and discourses of stakeholder groups. Additional interviewees were identified using a snowball sampling method by asking interviewees about their important partners and asking about stakeholders with whom they disagreed. This last question was meant to identify opposing views and ensure consideration of the full range of opinions. Interviewees were predominantly actors closely involved in policy making; thus some non-policy perspectives may not be fully included.

Interviews were recorded, transcribed and coded. Coding variables were developed deductively based on Marsh and Smith's conceptual framework of policy networks and policy change, which was modified to examine policy making in multiple, overlapping networks (Marsh & Smith, 2000; Toke & Marsh, 2003). Additional codes were added inductively as new concepts emerged in the analysis.

Major coding categories included the venues of the policy networks, the structures of the networks, actor categories, actors' traits, and actors' actions, characterizations of the process, and outcomes and impacts. The venue codes were the FDA's implementation, the GFSI network, and the LGMA network. Structural codes addressed the rules of participation, such as who may participate and how. Actor categories included consumer organizations, alternative agrifood organizations, the FDA, state/local regulators, and sectors of the food industry including but not limited to representatives of leafy greens and fresh produce growers, manufacturers, and retailers. The thirty seven interviewees were distributed across categories as shown in Table 1.

Table 1: Distribution of Interviewees across Sectors

Academic: 5	Attorney: 2	Government: 7	Media : 1	Civ. society: 10	Industry: 12
	Consumer: 1 Industry: 1	FDA: 1 USDA: 1 Senate staff: 2 State regulator: 3		Alternative: 6 Consumer: 5 Other: 1	Private regulator: 8 Manufacturing: 3 Fresh produce: 4
- numbers in the second row do not add up to the numbers in the top row because some individuals were included in multiple categories - among the non-government interviewees, five were former state or federal regulators					

Codes about actors' traits covered their strategic interests, resources, authority, and knowledge. Actors' actions were activities such as lobbying/advocacy, blocking/inaction, assuring or building trust, and learning. Codes about actors' characterizations of the processes included transparency, participatory-ness, difficult/easy, and speed. Finally, outcomes and impacts included policy choices, accountability, trust, conflicting or confusing policies, feasibility, and food safety. The data were analyzed in NVivo by cross-tabulating the seven categories so that I could ask questions such as what were different actor categories saying about outcomes in each of the venues?
Secondary materials, such as comments during the rulemaking process, media coverage, and public relations releases were also reviewed (but not coded and analyzed). This added additional understanding to the analysis of the interviews.

III. Overview of Papers

Enactment of the Food Safety Modernization Act: The US FDA within the Context of Interacting Public-Private Governance Processes

The first paper answers the question: What factors shaped the substantive outcomes in the Food Safety Modernization act and to what extent and in what ways do these outcomes restructure the regulatory roles of state and non-state actors? The paper predominantly draws on political science theories explaining policy change and the regulation and governance studies examining the interactions of public and private regulatory interactions.

The paper argues that to understand the choices that were made about provisions in the FSMA, we must look at actors' interactions and the outcomes that have occurred in other regulatory networks, including private standards regimes, courts, and other governmental regulatory agencies. Experiments with policy approaches to governing food safety, and observations about the consequences, shaped the policy options that were considered. When a policy window opened at the federal level, the lessons learned in those other venues led to conflicts in the enactment of the FSMA. Stakeholders hotly contested how broadly regulations should apply and the appropriate roles of state and private regulators in overseeing and enforcing food safety.

The resulting provisions in the FSMA expand FDA domestic and import authority, but also elevate the role of private regulators and industry. For FDA regulators, the law means trying to walk a line between independence and collaboration, while being responsive to a variety of conflicted stakeholders. For industry trying to manage global systems, the law could help by setting a floor for all producers but create increasing regulatory complexity. And for the private regulators, the legislation holds potential to increase their legitimacy as effective guardians of food safety.

Food Safety Governance in the Shadow of Overlapping Networks: Implementing the U.S. Food Safety Modernization Act

The second paper asks to what extent and in what ways are the various regulatory networks reshaping the transparency, inclusiveness and accountability of governance processes? It draws predominantly on regulation and governance studies and administrative law scholarship. It focuses on the implications of changing governance patterns for government administrators.

The paper argues that the overlapping networks have different systems of legitimacy and accountability which potentially generate redundant and inconsistent regulations. These potential conflicts create a tension for the FDA as a regulatory actor because there are strong institutional incentives to harmonize its regulatory activities with the other networks but inherent barriers to doing so are created by the differences in procedures for legitimacy and accountability.

The paper concludes that the proliferation of regulatory networks poses a larger problem, which is that they are aggravating power imbalances between different actors who have more or fewer resources to participate in governance processes. Current administrative law practices are ineffectually grappling with this. It remains unclear whether improvements in legitimacy and accountability might emerge as a result of greater competition between the networks, more integration, or some other transformative restructuring of the processes of governance.

Entrenching and Contesting Neoliberalism through the Food Safety Modernization Act

The third paper asks: To what extent and in what ways does enactment and implementation of the FSMA restructure relations and powers of actors in the agrifood system? This paper focuses on agrifood governance scholarship.

On the one hand, the law sets the United States further down a path of blurred public-private regulation that is being seen in a number of other countries. Though some private regulation is carried out by civil society, the law relies heavily on industry-developed and -driven mechanisms. Thus, it is arguably further entrenching patterns of corporate power that have been maligned in agrifood scholarship. On the other hand, alternative food systems advocates that were opposed to the bill's seemingly corporate agenda successfully achieved concessions in the bill to accommodate alternative food systems. Concurrently and following up on the final law, a number of private and state-led initiatives have emerged to provide technical and educational support to small and alternative food systems.

The paper concludes that the enactment and rulemaking of the FSMA largely reinforces corporate power, globalized food systems and neoliberal ideologies. Yet alternative agrifood systems advocates also used the process to successfully contest corporate agendas and are exploiting governance networks to pursue their interests. Nonetheless, scholarly critiques that contestation

activities often reinforce neoliberal ideologies and fail to effectively reform policies that support the current corporate food regime hold true in this case.

IV. Conclusion

The conclusion synthesizes the three papers and argues that the enactment of the FSMA sets the U.S. further down the path of public-private co-regulation and thereby legitimates a neoliberal-type proliferation of regulatory networks. This problematically threatens the capacities of resource-constrained actors to meaningfully participate in governance processes. The FDA, subject to traditional administrative procedure law, is ill equipped to handle the complex co-regulatory task it is assigned. Its efforts to ensure transparency and participation do little to redress the power imbalances because the provisions of the law do nothing to check the proliferation of private regulatory regimes. Further, there is little evidence from enactment or rule making that power relations have been meaningfully restructured.

The synthesized findings offer commentary on further directions for scholarly research. The conclusion suggests that regulation and governance and administrative law scholarship should give more attention to how neoliberal ideologies relate to the proliferation of networks and the ways the ideologies have pervaded the scholarship itself to normalize the idea of governing through multiple governance networks. On the other hand, the agrifood governance literature is critiqued for perhaps being too preoccupied with corporate power and neoliberal ideologies, causing it to miss opportunities to more agnostically examine how normative values and emerging governance patterns might potentially be re-conceptualized to achieve democratically legitimate regulation. Given the literatures' rich histories and complexities, these commentaries broadly oversimplify the foci and weaknesses of each literature. Understanding the nuances of their commonalities and disconnects in their study of common subjects and diversity of perspectives is an ambitious task. So

the conclusion also suggests a way to use the modified policy networks framework to organize the connections among the literatures in order to improve scholarly exchange and inquiry.

In reflecting on the praxis of governance from the privileged position of academia, the conclusion easily raises critiques and highlights shortcomings. There are no grand insights on how to be more effective, only a small note that alternative agrifood practitioners have achieved some restructuring of power dynamics and the best path forward for administrators is to at least keep muddling forward with efforts to increase transparency and participation in the federal administrative process. But both also can be cautioned to be aware of how their thinking and actions may re-entrench logics and processes that underlie problematic outcomes, thus only aggravating the problem they may seek to correct.

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Chapter 2: Enactment of the Food Safety Modernization Act: The US FDA within the Context of Interacting Public-Private Governance Processes

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Abstract

The United States' Food Safety Modernization Act (FSMA) revises the US Food and Drug Administration's regulatory authority. While expanding FDA's authority, the legislation replicates and relies on private systems of standards and third party audits, albeit with modifications. This article argues that public and private actors develop food safety regulations within multiple types of institutional venues, including private standards regimes, courts, congresses, and government regulatory agencies. It examines how interactions within each of these venues are shaped by stakeholders' interests and how the relevant subset of interactions within these venues ultimately shaped the FSMA. The article concludes by offering insights into what consequences these interactions and outcomes may have on the roles and capacities of affected stakeholders in food safety governance.

Introduction

Scholars recognize that governance – the setting, implementing, and enforcing of rules[1]– is done by complex networks of state and non-state actors.[2] The literature emphasizes that there has been a shift from governing through traditionally hierarchical mechanisms to a focus on networks and mechanisms that do not rely solely on traditional authority of the state,[3] though the actors replacing or displacing the state may not themselves be non-hierarchical. Food safety governance over the

[1] Anne Mette Kjaer, *Governance: Key Concepts* (Cambridge, Polity Press, 2004), at p. 10.
[2] Bob Jessop, "The Rise of Governance and the Risks of Failure: The Case of Economic Development" 50 *International Social Science Journal* (1998), pp. 29 *et sqq*., Rod A.W. Rhodes, "The New Governance: Governing Without Government" 44 *Political Studies* (1996), pp. 652 *et sqq.*
[3] Gerry Stoker, "Governance as Theory: Five Propositions" 50 *International Social Science Journal* (1998), pp. 17 *et sqq*.

last twenty to thirty years has followed this pattern, with food safety increasingly being governed through standards written by or at the behest of industry and enforced through third party audits.[4] The involvement of government actors in these standards and audits exists along a continuum, with some relying on government agencies to facilitate the rule setting and carry out audits.[5] A limited set of standards regimes are mandatory and written and enforced wholly through government agents.[6] This paper will examine the evolving roles and relationships of government and private actors as they have been shaped by the enactment of the United States Food Safety Modernization Act (FSMA).[7]

In the United States, some network complexity has long existed due to federalist arrangements between distinct levels of government and various public-private partnerships. In governing food safety, the federal Food and Drug Administration (FDA) has historically not had authority over food moving in intra-state commerce.[8] Instead, the agency collaborates with state regulators, public interest organizations, and industry to write a model food code that is variably adopted by states to regulate food wholly grown and sold within states. An example of public-private partnerships for governing food safety is the Interstate Shellfish Sanitation Conference, which coordinates private, state and federal regulation of shellfish.[9] A more recent food safety governance development has

[4] Jason Konefal, Michael Mascarenhas and Maki Hatanaka, "Governance In The Global Agro-Food System: Backlighting The Role Of Transnational Supermarket Chains" 22 *Agriculture And Human Values* (2005), pp. 291 *et sqq*., Maki Hatanaka, Carmen Bain and Lawrence Busch, "Third-Party Certification In The Global Agrifood System" 30 *Food Policy* (2005), pp. 354 *et sqq*., Spencer Henson and Thomas Reardon, "Private Agri-Food Standards: Implications For Food Policy And The Agri-Food System" 30 *Food Policy* (2005), pp. 241 *et sqq*.

[5] Ibid.

[6] See, e.g., Hazard Analysis and Critical Control Point Requirements for Juice, 21 C.F.R. § 120.1 (2014), Seafood, 21 C.F.R. § 123.6 (2014), Meat, 9 C.F.R. §304.3 (2014), and Poultry 9 C.F.R. §381.22 (2014).

[7] FDA Food Safety Modernization Act (FSMA), Pub. L. No. 111-353, 124 Stat. 3885 (2011), Amending the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 et seq. (1938).

[8] Food, Drug and Cosmetic Act, 21 U.S.C. § 303, prohibiting inter-state shipments of adulterated food.

[9] Interstate Shellfish Sanitation Conference homepage, available on the Internet at: http://www.issc.org/Default.aspx (last visited 2 Feb. 2015).

been the use of marketing orders to establish and enforce food safety standards for production of fruits and vegetables.[10]

Though governance recognizes regulation occurring through diverse and complex networks of actors, centralized hierarchical governments may continue to play a significant albeit altered role.[11] The enactment of the FSMA is a valuable juncture for examining shifting interplays between emerging private governance regimes, centralized federal regulation, and decentralized state and local governance. The FSMA is an historic revision of US food safety law[12] that expands FDA's authority but also builds on and relies on the pre-existing systems of private regulation. Most notably, the law requires FDA to replicate (but modify) preventive controls and produce safety standards like those already extensively used in the private sector and to consider the use of private audits for regulating imported foods. Other provisions, such as certain exemptions and limiting the use of private audits to imported food, were shaped by stakeholders' experience with private and quasi-private regulatory regimes. In this case study, although the federal government is exercising centralized authority, the FDA is being forced to act in concert with a network of partners and other regulatory actors. The federal regulations, once written, will not create a single, universal standard for production, but instead will become another set of regulations in an already well-populated universe of regulations.

The recognition of governance through complex networks means studies of regulation cannot just focus on a single, centralized government policy cycle. Rather, one must examine multiple, simultaneously revolving policy cycles. With multiple policy cycles, there are also more complex streams of politics, problem recognition, and policy development, so that windows to set policy can

[10] See e.g. the California and Arizona Leafy Greens Agreements, discussed in more detail *infra* section II.1.b. Marketing orders are public-private regulatory mechanisms developed in the 1930's to coordinate production and marketing of perishable crops.

[11] John Pierre and Guy Peters, *Governance, Politics and the State*, (New York, NY: St. Martin's Press 2000).

[12] Helena Bottemiller, "Historic Food Safety Bill Signed Into Law", Food Safety News, 5 January 2011.

open[13] in any number of institutional venues.[14] Venues may include Congress, the courts, state and federal regulatory agencies, private standard setting bodies, harmonizing organizations, and others. Actors and events in a particular stream, or the opening or closing of a policy window, may unexpectedly affect the policy making streams in other venues and add to the complexity of understanding how governance choices occurred.

To deal with this complexity, this paper focuses on the interactions of sub-sets of actors within the institutional venues where regulatory decisions are contested, decided, and enforced. While food safety governance is carried out by a complex network of state, industry, and civil society actors, only sub-sets of those actors may effectively participate in any given venue at any given time. Actors may concurrently fulfill different roles in the policy process depending on which venue is in play. Thus, as actors in a private regulatory regime are implementing and evaluating a regulation, they may simultaneously be involved in the standard setting phase for a public regulatory regime. This has been the case with the FSMA. For example, manufacturers who have been subject to private standards and produce growers who were setting standards enforced by state and USDA agents both called for FDA to take on the role of adopting and enforcing standards for the production of food and oversight of auditors. Likewise, the auditors responsible for enforcing standards are simultaneously advocating for greater reliance on private audit systems while also

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[13] John Kingdon, *Agendas, Alternatives and Public Policies,* 2nd ed. (New York, NY: Longman 2003)

[14] The term 'venues' draws from Baumgartner and Jones research into how actors interactions in venues can be used to contest a policy image and destabilize policy networks. As they note:

> There are no immutable rules that determine which institutions in society will be granted jurisdiction over particular issues. Depending on the issue and on how it is understood by those potentially involved, it may be assigned to an agency of the federal government, to private market mechanisms, to state or local authorities, to the family, or to any of a number of institutions. We term this the venue problem. Each venue carries with it a decisional bias, because both participants and decision-making routines differ. When the venue of a public policy changes, as often occurs over time, those who previously dominated the policy process may find themselves in the minority, and erstwhile losers may be transformed into winners.

Frank Baumgartner and Bryan Jones, "Agenda Dynamics And Policy Subsystems" 53 *The Journal of Politics* (1991), pp. 1044 *et sqq*., at p. 1047.

rewriting private standards for the auditors' competencies in response to some of the same issues that catalyzed the FSMA.

Identifying and accurately categorizing the primary influential stakeholders can help in examining how actors' identities, interests and relationships shape policy choices and how the regulatory systems relate to one another.[15] Scholars commonly divide actors into state, market, and civil society actors. These broad categories oversimplify actors' roles within the categories as well as how porous the categories have become. Therefore, it is useful to distinguish between different actors within each category.[16] During the enactment of the FSMA, noteworthy differences within each of these categories ultimately had a significant impact on the law. Within the 'state actors' category, the three most important ones to consider for this paper are members of Congress, the US Food and Drug Administration officials, and state departments of agriculture representatives. Within 'market actors', although the legislative process saw significant commonalities, there were subtle differences between retailers, importers and distributors, manufacturers, growers, and auditing firms in terms of what they considered most significant. In the civil actors' categories, there was an unexpected and dramatic rift between consumer groups and alternative food systems advocates. The importance of these distinctions will become evident as the venues where they interact are discussed.

Using the trope of venues allows one to focus on how certain actors' interactions within each venue shape stakeholders' objectives, and in turn how those actors then adjust their strategy and ultimately shape regulatory practices in other venues in which they participate. To examine how private regulatory regimes are shaping public food safety regulation in the United States, this paper

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[15] Fabrizio Cafaggi, "The Architecture Of Transnational Private Regulation" 2011/12 *European University Institute Working Papers* (2011); Fabrizio Cafaggi, "New Foundations Of Transnational Private Regulation" 38 *Journal of Law and Society* (2011) pp. 20 *et sqq*., 45; Tetty Havinga, "Conceptualizing Regulatory Arrangements: Complex Networks of Actors and Regulatory Roles" in Tetty Havinga, Frans van Waarden and Donal Casey, *The Changing Landscape of Food Governance* (Cheltenham, Edward Elgar 2015), p. 19-36..

[16] Havinga, "Conceptualizing Regulatory Arrangements", *supra* note 15.

focuses on how the prior interactions between sub-networks of actors in other regulatory venues shaped what concerns and strategies actors brought to enactment of the FSMA, which occurred in the Federal congressional venue. This paper begins with analysis of the important venues where actors previously interacted and what concerns they took from those venues. It then turns to discussing how those interactions shaped the enactment process and final provisions that made it into the law. Finally, this paper discusses how the FSMA reshapes and impacts the roles and capacities of actors in the new and pre-existing regulatory regimes.

I. Interactions Pre-FSMA

Before the process of enactment of the FSMA, many of the key actors were members of networks engaged in governance in other venues. Most prominently, manufacturers and fresh produce growers were being subjected to private standards regimes driven by retailers and multi-national food companies operating in globalized markets.[17] Additionally, fresh produce growers were implementing industry-wide regulations through quasi-public mechanisms.[18] Though less prominent, consumers and the FDA were also interacting with and shaping the evolution of these regimes through their exercise of power in the US court system. Finally, international standards and dispute resolution bodies cast a shadow over the enactment phase to the extent that stakeholders were concerned about how US law could be affected by global trade rules. Successes and failures of public and private actors in each of these venues impacted the provisions stakeholders prioritized in the enactment of the FSMA.

1. Industry Driven Regulatory Regimes

[17] Hatanaka, Bain and Busch, "Third-Party Certification In The Global Agrifood System", *supra* note 4, Konefal, Mascarenhas and Hatanaka, "Governance In The Global Agro-Food System", *supra* note 4.
[18] Diana Stuart, "Science, Standards, And Power: New Food Safety Governance in California" 25 *Journal Of Rural Social Sciences* (2010), pp. 111 *et sqq.,* Hoy Carman, "California Farmers Adapt Mandated Marketing Programs to the 21st Century" 61 *California Agriculture* (2007), pp. 177 *et sqq.*.

Private regulation has encountered two recurring problems. First, the proliferation of private standards and audit requirements created multiple audits that were time consuming and expensive. The different audits showed little evidence of providing unique advantages or superior effectiveness relative to one another. Second, recurrent food borne illness outbreaks, some associated with companies that had received seemingly superior scores from private audit firms, eroded consumer and industry confidence in the effectiveness of these private audit regimes. [19] Initially, industry sought to reform the private standard setting and enforcement mechanisms to shore up the effectiveness and perceived legitimacy of the private regimes through programs discussed here such as the Global Food Safety Initiative and the Leafy Greens Marketing Agreement.[20] Ultimately, industry allied with consumer groups to call for the enactment of the FSMA, while also continuing to pursue food safety regulation through industry organized schemes.

a. GFSI Schemes: Evolution, Breakdown, and Calls for the FSMA

The Global Food Safety Initiative (GFSI) describes itself as a benchmarking system initiated in 2000 by the Consumer Goods Forum, an international trade association of retailers and manufacturers, to address the proliferation of standards and audits for food manufacturers. This collaboration attempts to reduce the number of audits required of producers by establishing minimal acceptable requirements "to credibly determine equivalency between food safety schemes, whilst leaving

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[19] Gallup polls during this time period showed little change in consumer perceptions regarding food safety. Gallup, "Nutrition and Food", available on the Internet at: http://www.gallup.com/poll/6424/Nutrition-Food.aspx (last visited 2 Feb. 2015). However, industry and consumer group publications were widely reporting declining consumer confidence in the US food supply. See, e.g., Peter D. Hart Research Associates and Public Opinion Strategies, "Results Of A National Survey On Produce Safety", available on the Internet at: <http://www.pewtrusts.org/~/media/legacy/uploadedfiles/phg/content_level_pages/reports/PSPRPTHartResearchSurveypdf.pdf> (last visited 2 Feb. 2015), Rory Harrington, "Bill bids to strengthen 'dangerous' US food safety regimes", Food Navigator USA, 29 May 2009, available on the Internet at <http://www.foodnavigator-usa.com/Regulation/Bill-bids-to-strengthen-dangerous-US-food-safety-regime> (last visited 2 Feb. 2015), Jenny McTaggart, "Food Safety: Safety Dance", Progressive Grocer, 15 Oct. 2007, available on the Internet at: http://business.highbeam.com/4122/article-1G1-170296861/cover-story-food-safety-safety-dance (citing FMI research showing consumer confidence at 18 year low.)

[20] The LGMA is not technically a private regulatory regime. Instead, it is a regulatory tool that was developed under state-level marketing agreement laws. Since it was industry initiated and driven, but overseen by public process, it is a quasi-public-private regulatory arrangement.

flexibility and choice in the marketplace."[21] Over its tenure, GFSI has made progress on harmonizing standards and auditing practices, while also pushing for continuous improvement.[22]

In 2008, Wal-Mart began to require GFSI recognized audits of certain suppliers, catalyzing more widespread adoption of GFSI in the United States.[23] Consequently, manufacturers and growers selling to large buyers were told to achieve increasingly stringent private standards while their competitors and other segments of their industry were held to outdated public food safety standards. Buyers, meanwhile, were not vigorous about restricting purchases to GFSI-certified producers, which undermined incentives to invest in food safety.[24] As outbreaks of foodborne illnesses continued through the 2000's, industry trade associations such as the United Fresh Produce Association, the Grocery Manufacturers Association, and the Food Marketing Institute all turned to supporting the idea of food safety legislation reform to hold everyone to a minimum set of common standards.[25]

There were differences between consumer groups and industry groups over the extent to which FDA should rely on or regulate private regulation. The history of outbreaks associated with privately audited foods had seriously eroded trust in the quality of the standards and the quality of the inspections and consumer groups saw enforcement of food safety as a quintessentially

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[21] GFSI, "What Is GFSI", available on the Internet at: <http://www.mygfsi.com/about-us/about-gfsi/what-is-gfsi.html> (last accessed on 17 October 2014).

[22] John G. Surak and Kathy L. Gombas, "GFSI's Role in Harmonizing Food Safety Standards", Food Safety Magazine, June/July 2009.

[23] Wal-Mart, "Wal-Mart Becomes First Nationwide U.S. Grocer to Adopt Global Food Safety Initiative Standards," 4 February 2008, available on the Internet at: <http://news.walmart.com/news-archive/2008/02/04/wal-mart-becomes-first-nationwide-us-grocer-to-adopt-global-food-safety-initiative-standards> (last accessed on 17 October 2014).

[24] Jim Prevor, "Buyer Led Food Safety Initiative Recap", Perishable Pundit, available on the Internet at: < http://www.perishablepundit.com/index.php?hot=buyer-led> (last accessed on 13 October 2014).

[25] See, e.g., "United Fresh Statement on Introduction of the FDA Food Safety Modernization Act of 2009", 9 March 2009, available on the Internet at: <http://www.unitedfresh.org/news/797/united_fresh_statement_on_introduction_of_the_fda_food_safety_modernization_act_of_2009_> (last accessed on 17 October 2014), "Grocery Manufacturers Association And Food Marketing Institute Call For Passage Of Food Safety Bill", 24 November 2010, available on the Internet at: <http://www.gmaonline.org/news-events/newsroom/grocery-manufacturers-association-and-food-marketing-institute-call-for-pas/> (last accessed on 17 October 2014).

government role.[26] Industry representatives, meanwhile, argued that private standards and auditing schemes were effective. They expect private auditors to be as effective as (if not superior to) government inspectors due to auditor accreditation and economic accountability.[27] Discussions of the appropriate role of private regulatory regimes within a public system were complicated by the fact that two of the major outbreaks driving the bill – separate salmonella outbreaks in peanut butter and eggs – were traced back to domestic facilities that had received seemingly superior ratings from private audit firms.[28] Yet government officials had been in those facilities as well and failed to detect transgressions and take actions to prevent the outbreaks.[29] Consumer groups saw these incidents as symptomatic of the flaws inherent in a private self-regulatory system combined with failures resulting from under-resourced public regulatory regimes. Although industry joined with consumer groups in calling for stronger FDA oversight, industry spokespersons also argued for the quality and effectiveness of industry-developed regulatory regimes.[30] Interviews with industry actors have suggested that the outbreaks were caused by anomalous bad actors and that government is no better at detecting, especially those

[26] See Patricia Sabatini, "Calls Grow For Tougher Food Safety Regulations," Pittsburgh Post-Gazette , 7 October 2009, at FOOD p. A1, (quoting CSPI attorney Sarah Klein saying "the FDA needs tough, 21st-century tools to deal with centralized, modern production…we cannot rely on the good will of the food industry.")
[27] See Timothy Lytton and Lesley Mcallister, "Oversight In Private Food Safety Auditing: Addressing Auditor Conflict Of Interest" 2014 Wisconsin Law Review (2014), pp. 290 *et sqq.*
[28] The Peanut Corporation of America and Decoster Farms had both received "superior" ratings from AIB shortly before their products sickened hundreds. See *The Outbreak of Salmonella in Eggs, Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 111th Congress (2010) (statements by Peter DeCoster, co-owner of DeCoster Farms; statement by DeGette, vice-chairman, H. Comm. on Energy and Commerce) at p. 82. See also Andrew Martin, "Peanut Plant Says Audits Declared it in Top Shape", New York Times, 5 February 2009, at p. B10, Michael Booth and Jennifer Brown, "Producers Seldom Hear of Food Safety Issues from their Private Auditor", The Denver Post, 30 October 2011, at p. A1.
[29] Alan Judd, "Peanut Scare Exposes Flaws in Inspections; Food Safety Net: Regulation Gaps Found at Georgia Processing Plant Will Likely Come Under Scrutiny In Upcoming Congressional Hearings*", Atlanta Constitution Journal,* 30 January 2009, at p. 1A.
[30] See, e.g., *How Do We Fix Our Ailing Food Safety System? before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 111th Congress* (2009) (statement of Tom Stenzel, President and CEO, United Fresh Produce Association), *Keeping America's Families Safe: Reforming the Food Safety System, before the S. Comm. on Health, Education, Labor, and Pensions*, 111th Congress (2009) (statement by Michael Roberson, Director of Corporate Quality Assurance Publix Markets Inc., on behalf of the Food Marketing Institute).

who knowingly disregard standards and hide food safety violations, as happened in the Peanut Corporation of America incident.[31]

Many, including FDA officials and consumer groups, acknowledged the necessity of relying on private audits as supportive of the FDA's food safety role, given the agency's limited resources and constrained authority in foreign countries. The Center for Science in the Public Interest (CSPI), the Grocery Manufacturers Association (GMA), and the FDA all put out proposals that envisioned FDA relying on private auditors to enhance governance of imported foods. However, there was disagreement regarding what FDA's and private auditors' roles should be domestically. Consumer groups wanted significantly expanded authorities for FDA, including requiring process controls for all manufacturers, increased records access, more diverse penalties, and increased enforcement authority for FDA – with no role for private audits. GMA's plan on the other hand called for little more than increasing FDA's capacity to collect data and transition to risk-based enforcement. FDA's plan fell in the middle, calling for increased reliance on manufacturers through requiring food-safety plans for high risk foods, and partnering with private accredited auditors to enforce food safety domestically and abroad.[32]

b. Produce Standards and the Leafy Greens Marketing Agreements

In the early 1990s, produce associations began to recognize outbreaks being associated with fresh produce and moved to develop voluntary guidelines – known as Good Agricultural Practices (GAPs) – which can be enforced through private audits or through programs run by states and the United States Department of Agriculture. Being voluntary, the programs are not universally employed and

[31] Anonymous interviews conducted by the author with civil society, government, and industry representatives between October 2013 and September 2014. Interview subjects were initially identified using news stories and legislative testimony from the FSMA; further interview subjects were identified through snowball sampling by asking initial subjects for other important actors to speak with.

[32] See Caroline Smith-Dewaal and David W. Plunkett, "Building A Modern Food Safety System For FDA Regulated Foods", (Center For Science In The Public Interest, 2009), "Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply" (Food And Drug Administration, 2007); "A Commitment to Consumers to Ensure the Safety of Imported Foods: Four Pillars of Public-Private Partnership" (Grocery Manufacturers of America).

various segments of the produce industry have lost millions of dollars following outbreaks associated with product from a single grower.[33]

In 2008, tomato growers in Florida claimed to lose an entire season's crop and revenue when a *Salmonella* Saintpaul outbreak was erroneously initially attributed to tomatoes from Florida. The industry had an extensive food safety and trace back regime which they argued to FDA officials demonstrated the safety of their product. Despite the system, FDA believed that their epidemiology sufficiently justified issuing consumption warnings that diminished demand for the crop and caused Florida tomato growers significant economic harm. The tomato growers were ultimately proven right when the outbreak was conclusively connected to hot peppers.[34] For the produce industry, this incident highlighted the need to have FDA recognize industry's food safety practices.

Two years earlier, following a particularly deadly and widespread outbreak of E. coli associated with leafy greens from California,[35] the California and Arizona leafy greens industries initiated the California and Arizona Leafy Greens Marketing Agreements (LGMA).[36] In response to plummeting consumer demand for leafy greens, the industry initiated a request to the California Department of Agriculture to develop the marketing agreements through a public proposal, feedback and voting process.[37] This approach was explicitly chosen as the fastest way to respond to retailer and consumer demands for food safety, while also bringing government officials onto the farm to ensure confidence in the quality of the inspections.[38] The process was not uncontroversial, with small farms and conservation advocates raising concerns about the economic and environmental

[33] See Luis A. Ribera et al., "Costs of Foodborne Illness Outbreaks for Vegetable Producers", EHT-027 *Texas A&M Agrilife Extension* (December 2013).
[34] See Vanessa Wong, "Rotten Tomatoes: Farmers Pay the Price for A False Food Safety Warning", Bloomberg Business Week, 29 September 2014.
[35] Jesse Mckinley, "Center Of E. Coli Outbreak Is Also Center Of Anxiety", New York Times, 25 September 2006, at p. A14.
[36] Each state technically has a separate LGMA, because they are developed under state law. However, it is common to refer to them jointly as the LGMA.
[37] California Marketing Act of 1937, 21 FOOD & AGRIC. § 58601-58624 et seq., 3 Ariz. Rev. Stat. § 3-401 et seq.
[38] Scott Horsfall, "California Leafy Greens Marketing Agreement Emerges as a Model Program for Food Safety", Food Safety Magazine, August/September 2008.

impacts of the rules being written.[39] Another criticism was that if all producers and handlers failed to sign on to the agreement, the standards would be ineffective at ensuring food safety and rebuilding consumer trust.[40] At the same time, the California legislature considered legislation to mandate standards and increase agency enforcement over leafy greens. This was out of concern that industry self-regulation through the LGMA would be ineffective.[41]

In the end, the LGMA was adopted and it established metrics for evaluating safety of production in fields in California and Arizona, with compliance verified through audits carried out by government inspectors. The agreements have gained extensive adoption, with approximately 90 percent of greens grown in the US subject to either the California or Arizona agreement.[42] Nonetheless, the remaining leafy green producers across the country remained free of, and generally opposed to, metrics for safety of leafy greens. In a reprise of the issues, a national leafy greens agreement overseen by the US Department of Agriculture, was proposed but ultimately dropped due to the enactment of the FSMA.[43]

Despite the extensive efforts at private regulation and partnerships with state and federal agriculture departments, important produce trade associations took the position that universally enforced food safety standards written and recognized by FDA officials were needed.[44] However, opposition from small farm and sustainable agriculture advocates stemming from experiences with

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[39] See Stuart, "Science, Standards, and Power", *supra* note 13 for an in-depth discussion of the motivations and controversies involving the LGMA. Efforts have since been underway to address some of these issues. See, e.g., Karen Lowell, Jeffrey Langholz, and Diana Stuart, "Safe and Sustainable: Co-Managing for Food Safety and Ecological Health in California's Central Coast Region" (The Nature Conservancy of California and the Georgetown University Produce Safety Project, 2010).

[40] See Jim Prevor, "Is the California Marketing Agreement a Triumph or a Failure?", Perishable Pundit, 9 February 2007.

[41] See Rong-Gong Lin II, "Senator Seeks New Oversight of Greens", Los Angeles Times, 12 October 2006, available on the Internet at: < http://articles.latimes.com/2006/oct/12/local/me-spinach12> (last accessed on 31 October 2014).

[42] California Leafy Greens Products Handler Marketing Agreement, "About Us", available on the Internet at: < http://www.lgma.ca.gov/about-us/> (last accessed on 17 October 2014).

[43] National Marketing Agreement Regulating Leafy Green Vegetables; Termination of Proceeding on Proposed Marketing Agreement, 78 Fed. Reg. 234 at 73111.

[44] See Jim Prevor, "PMA and United Fresh Agree on Federal Food Safety Regulation", Perishable Pundit, 24 May 2007.

the LGMA nearly killed the legislation. The compromise that was worked out, exempting certain small farms and facilities selling directly to consumers within a geographic region, was opposed by industry, consumer groups, and the FDA. The law passed containing the exemption because of the perceived importance of achieving legislative reform.[45]

2. Courts

State and federal courts in the United States are an important and under-attended to venue where the public and private regulatory regimes meet. First, courts are a venue where the rules concerning interactions between food safety regulators and regulated entities are partly written and enforced. The Food, Drug and Cosmetic Act required the FDA to obtain a court order to mandate recall of a product,[46] thereby limiting FDA's enforcement flexibility. Though the agency also had criminal sanctions authority, the FDA rarely used it.[47] New enforcement provisions in the FSMA will give the agency more flexibility for enforcing food safety but have raised concerns among industry that the agency may abuse its power because systems of judicial accountability have been bypassed.[48] Similarly, industry suits challenging FDA's exercise of power as unconstitutional takings of property and inappropriate restrictions on trade have attempted to further limit FDA's exercise of authority. The suits have, so far, been relatively unsuccessful.[49] However, there is concern these suits could have chilling effects on the agency's enforcement strategies.[50]

Courts have also been an important venue for consumers to pursue accountability in the food system when government officials have failed to detect and/or deter unscrupulous and inadvertent

[45] See Bill Marler, "Once GOP Is In Kitchen, Food Safety Is Toast", Food Safety News, 3 December 2010.
[46] Food Drug and Cosmetic Act, 21 U.S.C. § 331 et seq. (2009).
[47] Dan Flynn, "Reprieve from Criminal Prosecutions May Be Ended For Food Execs", Food Safety News, 4 May 2012.
[48] See David Acheson, "FDA FSMA Facility Suspension Powers – Appropriate or Abusive?", 20 March 2014, available on the Internet at: <http://achesongroup.com/2014/03/fda-fsma-facility-suspension-powers/> (last accessed on 12 October 2014).
[49] Dan Flynn, "Top Food Safety Stories Of 2011: No. 5", Food Safety News, 27 December 2011, Dan Flynn, "Tomato Growers Lose 'Takings' Lawsuit against FDA", Food Safety News, 22 September 2014.
[50] Mary Clare Jalonick, "Suit Could Chill Government Efforts To Keep Food Safe", Bloomberg Businessweek, 31 August 2011.

bad actors.[51] This exposure to legal liability led retailers, manufacturers, and growers to adopt private and voluntary standards and audit schemes to regulate food safety.[52] In the United States, consumers can potentially hold everyone throughout the supply chain liable for injuries from contaminated foods. However, standards and audit requirements, combined with indemnity clauses in contracts, have the effect of shielding retailers from liability. [53] Consequently, accountability in the supply chain does not fall on the entities whose financial clout significantly influences compliance with food safety requirements. Though the FSMA significantly alters FDA's authority and consequent relationship to the regulated industry within the courts, it does little to change the liability dynamics between buyers and sellers.

3. International Venues

The final venues to be discussed are the World Trade Organization and the Codex Alimentarius Commission. The Agreement on the Application of Sanitary and Phytosanitary Measures of the WTO requires countries' food safety standards to conform to standards written by the Codex.[54] One standard that Codex has written is for Hazard Analysis and Critical Control Point Systems (HACCP). Among the actors who participate in Codex are FDA officials, who recognize that the standards set in Codex can constrain how the agency regulates. When the FSMA was enacted, rather than require HACCP systems of all manufacturers, Congress chose to require "risk based preventive controls

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[51] See, e.g., *Hearing to Review Current Issues in Food Safety, Hearing Before the H. Committee On Agriculture,* 111th Cong. (2009) (Statement of Rep. Bob Goodlatte, Member, House Comm. On Agriculture). "That incident [the PCA outbreak] was not the result of inadequate legal authority or even inadequate regulation. It was the result of intentional disregard of food safety standards by the food processor and a complete failure of the FDA to enforce its own regulations."

[52] Linda Fulponi, "Private Voluntary Standards In The Food System: The Perspective Of Major Food Retailers In OECD Countries" 31 *Food Policy* (2006), pp. 1 *et sqq*., Hatanaka, Bain and Busch, "Third-Party Certification In The Global Agrifood System", *supra* note 4.

[53] See Bill Marler, "Why Food Retailers Really Don't Care", 14 June 2013, available on the Internet at: <http://www.marlerblog.com/lawyer-oped/why-food-retailers-really-dont-care/#.u2z4c_ldwso> (last accessed on 4 May 2014), Bill Marler, "What Do Cantaloupe and Baseball Have In Common? At Least a Baseball Won't Kill You", Food Safety News, 17 August 2013.

[54] Uruguay Round of Multilateral Trade Negotiations (1986- 1994) , Agreement on the Application of Sanitary and Phytosanitary Measures (WTO- GATT 1994), 15 April 1994, in force 01 Jan. 1995, Art. 12.3.

plans" which are HACCP-like. One interviewee suggested this was so that FDA would not be constrained to conforming to Codex standards. Several others noted that the provision means FDA's regulations will not necessarily be consistent with globally recognized standards, including the private GFSI regulations that are based on Codex.

Another venue to note is the International Organization for Standardization (ISO). The ISO has not had a mentionable impact on enactment of the FSMA. However, applicable ISO standards are used by the GFSI to assess food safety schemes.[55] The accreditation of certifying bodies to ISO standards is seen as important for ensuring the quality of private auditors.[56]

II. The Enactment of the FSMA

1. The Process

Consumer advocates, including members of Congress, had been pushing for food safety legislation reform for over 20 years by the time the FSMA was enacted. A series of high-profile incidents, including the outbreak of E. coli in spinach and the recalls of peanut butter and eggs[57] and many others,[58] as well as an incident involving melamine in products from China in 2007,[59] created the perception of a food safety problem and deteriorating consumer confidence in food companies.[60] At the same time, consumer groups, industry, and the FDA all worked to develop policy white papers on what legislative reform was needed.[61]

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[55] *GFSI Guidance Document*, 6th ed. (The Global Food Safety Initiative, 2011).
[56] Lytton And Mcallister "Oversight In Private Food Safety Auditing", *supra* note 21.
[57] Discussed *supra* section II.1.
[58] See Dewaal and Plunkett, "Building a Modern Food Safety System", *supra* note 32, at p. 2 for a list of other outbreaks.
[59] See Patricia Sullivan, "Another Pet Food Ingredient is Contaminated by Chemical", 20 April 2007, at p. A8, Gardiner Harris and Andrew Martin, "U.S. Blocks Products with Milk from China", New York Times, 14 November 2008, at p. A18.
[60] See, e.g., Peter D. Hart Research Associates and Public Opinion Strategies, "Results Of A National Survey On Produce Safety", Rory Harrington, "Bill bids to strengthen 'dangerous' US food safety regimes", Jenny McTaggart, "Food Safety: Safety Dance" *supra* note 19.
[61] See Smith-DeWaal and Plunkett, "Building a Modern Food Safety System", "Food Protection Plan", "A Commitment to Consumers to Ensure the Safety of Imported Foods " *supra* note 32. The FDA specifically

Following the melamine outbreak, a federal policy window began to crack open as a series of Congressional hearings beginning in 2007 revealed that the FDA was overwhelmed, under-resourced, and lacked authority to react and respond to an increasingly complex and globalized food system.[62] In 2009, following the election of a Democratic Congress and President, momentum for the legislation accelerated with a bill moving through the House of Representatives rather quickly. Recognizing that a critical opportunity was emerging to change federal food safety policy, the Pew Charitable Trusts invested significant resources in consumer groups' advocacy efforts. Meanwhile the Grocery Manufacturers Association hired a key lobbyist – Scott Faber – whose experience and relations on Capitol Hill, as well as history working for the Environmental Working Group, made him a strong, trustworthy advocate for the bill.[63]

Despite the momentum, the bill stalled in the Senate while Democrats worked to push through universal healthcare finance reform legislation. The senate version of the bill was not taken up until late 2010 near the end of the Congressional session, when it had to compete with many other hot button issues such as "the Dream Act" and "Don't Ask, Don't Tell".[64]

Because of the November 2010 elections, control of the House would switch to Republicans in 2011, so it was believed that if legislation was not passed under the 111th Congress, it would not

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created the position of Association Commissioner of Food Protection and appointed David Acheson to conduct an internal assessment what resources and authorities FDA would need to more effectively govern food safety. FDA News Release, "FDA Commissioner Announces New Food Safety Protection Position," 1 May 2007, available on the internet at: <http://www.fda.gov/newsevents/newsroom/pressannouncements/2007/ucm108903.htm> (last accessed on 07 January 2015).

[62] See, e.g., *Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?", Hearing before H. Comm. on Energy and Commerce*, 111th Congress (2010).

[63] According to one interview, "GMA also brought on a lobbyist who had good relations with the consumer groups, and that was Scott Faber. Scott's very effective lobbyist, very good, very knowledgeable, and strong personality with good relations on the hill, but at the same time he had a very good reputation with our groups because he came out of the environmental working group."

[64] See Bill Marler, "FSMA: The End of My 20-Year Law Practice? Let's Hope So!", 19 March 2014, available on the Internet at: <http://www.marlerblog.com/case-news/fsma-the-end-of-my-20-year-law-practice-lets-hope-so/#.u1a7r_ldwgc> (last accessed on 17 April 2014).

happen.[65] Though there had been general, well developed consensus among industry, academics, legislators and consumer groups in the early stages of the enactment, this delay was critical. Alternative food systems advocates allied with a cohort of sympathetic Senators to threaten blockage of the entire bill if their concerns were not addressed. This group was able to extract exemptions that were opposed by FDA, industry, and consumer groups.[66] Had there been more time, and had these groups been more engaged in other venues and phases of the policy development process, it is conceivable that a more palatable compromise of scaled regulation or technical assistance would have received more traction as a policy alternative.

In the end, the bill was passed so late in the legislative session that there was no opportunity to resolve differences between the Senate and House bills, leading to a wholesale adoption of the Senate bill as written.[67] Consequently, the exemptions for small scale producers were included, while provisions such as fees to fund implementation of the bill were not.

2. Final Provisions in the Law

The FSMA makes three significant changes to FDA authority: the FSMA requires FDA to develop a preventive food safety system; it enhances FDA inspection, compliance, and recall authority; and it authorizes FDA to increase oversight of importers and their foreign suppliers through an audit and certification scheme.[68] The law does not contain provisions for funding the bill, which has potential implications for FDA's role and ability to implement the law.

a. Prevention

[65] See Marler, "Once GOP is in Kitchen", *supra* note 38.
[66] Helena Bottemiller, "Food and Ag Groups Rally Against Tester Amendment", Food Safety News, 16 November 2010.
[67] Bill Marler, "FSMA: The End of My 20-Year Law Practice? Let's Hope So!", *supra* note 64.
[68] Food and Drug Administration, "Background on the Food Safety Modernization Act (FSMA)", available on the Internet at: <http://www.fda.gov/food/guidanceregulation/fsma/ucm239907.htm> (last accessed on 12 October 2014). For a more in depth discussion of the key provisions, and discretion left to FDA for fleshing out the rules, see Kristin Eads and Jennifer Zwagerman, "In Focus: Examining The New FDA Food Safety Modernization Act" 33 Hamline Journal of Public Law and Policy (2011) , pp. 123 *et sqq.*; Debra Strauss, "An Analysis Of The FDA Food Safety Modernization Act: Protection For Consumers And Boon For Business" 66 Food And Drug Law Journal (2011), pp. 353 *et. sqq*.

There are two key components to increasing prevention. First, FDA must develop Hazard Analysis and Risk Based Preventive Controls (HARPC) for food processing facilities.[69] The law does, however, direct the agency to review preventive control programs such as HACCP that already exist, to ensure that the HARPC regulations are at least consistent with standards that are already in use."[70] Canons of legal interpretation of this language may require FDA to develop a program that relies on HACCP but is distinct from it.

Second, the agency must develop standards for the growing and handling of fresh produce.[71] Although FDA had previously worked with some commodities to develop guidance on preventing bacterial contamination,[72] this is a significant new authority and substantially broader area of regulation for FDA. Though USDA-operated GAP programs continue to exist as an available voluntary certification program, ultimate authority for evaluating compliance with public food safety standards has been assigned to the FDA.

As a result of the campaigns by alternative food systems advocates, there are limited exemptions to these requirements for small scale farms and manufacturers who primarily market through direct, local sales.[73] Though FDA retains authority to inspect and sanction these entities in the event of an outbreak,[74] it is expected that the states will generally oversee these smaller, exempt growers and manufacturers under state-level food safety laws. Buyers, including retailers and institutions such as schools and hospitals, are also likely to require certification to the standards, despite the

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[69] FSMA, *supra* note 7, § 103 (to be codified at 21 U.S.C. §350(G)).
[70] FSMA, *supra* note 7, § 103(N)(5).
[71] FSMA, *supra* note 7, § 105 (to be codified at 21 U.S.C. §350(H)).
[72] See FDA, "FDA Issues Draft Guidances for Tomatoes, Leafy Greens and Melons", available on the Internet at: <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/produceplantproducts/ucm174086.htm> (last accessed on 12 October 2014).
[73] See National Sustainable Agriculture Coalition, "Food Safety Action Alert", 10 November 2010, available on the Internet at: <http://sustainableagriculture.net/blog/food-safety-action-alert-2/> (last accessed on 12 October 2014), National Sustainable Agriculture Coalition, "Senate Passes Food Safety Modernization Act", 30 November 2010, available on the Internet at: <http://sustainableagriculture.net/blog/senate-passes-food-safety-bill/> (last accessed on 12 October 2014).
[74] See Kelly Damewood, "FSMA's Small Farm Exemption Has Its Limits", Food Safety News, 17 December 2013.

exemptions.[75] FDA has historically relied on states to carry out significant portions of their inspections, and FDA has been criticized for failing to oversee the quality of states' programs. This calls into question the extent to which FDA's reliance on other entities will be effective.[76]

b. *Inspection and Recall Authority*

Under the FSMA, FDA has been given authority to inspect records,[77] mandate recalls[78] and withdraw a facility's registration.[79] Previously, the agency could only request that companies issue recalls (which companies for the most part did) or had to pursue a court order to mandate one. As a result FDA inspections had to be focused on building a court case and could not always be carried out in a manner that achieved immediate corrections. Under FSMA, the agency can threaten to withdraw a registration in order to secure compliance with the law. Indeed, the agency has used the threat and actual suspension of registration to deal with problematic companies.[80] The agency has also increased its use of judicial enforcement, bringing criminal prosecutions against the Peanut Corporation of American executives for the 2008 peanut butter recall and the owners of a cantaloupe farm that caused the most deadly foodborne illness outbreak of the last 30 years in the summer following enactment of the FSMA.[81]

c. Third Party Verifications

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[75] See Food and Drug Administration, "FDA Answers Farmers' Questions: Answers to Questions about the Original FSMA Produce Safety Proposed Rule from Mike Taylor, Deputy Commissioner for Foods and Veterinary Medicine", available on the Internet at: <http://www.fda.gov/food/guidanceregulation/fsma/ucm358090.htm> (last accessed on 17 October 2014).
[76] See "FDA Oversight Of State Food Inspection Programs: A Call For Greater Accountability", OEI-01-98-00400 (Department of Health and Human Services, Office of Inspector General, June 2000), "Vulnerabilities In FDA's Oversight Of State Food Facility Inspections", OEI-02-09-00430, (Department of Health and Human Services, Office of Inspector General, December 2011), Dewaal and Plunkett, "Building A Modern Food Safety" *supra* note 32.
[77] FSMA, *supra* note 7, § 101 (To Be Codified at 21 U.S.C. 350c(A))).
[78] FSMA, *supra* note 7, § 206 (To Be Codified At 21 U.S.C. 341 Et Seq.).
[79] FSMA, *supra* note 7, § 102(B) (To Be Codified at 21 U.S.C. 350d(A))).
[80] See Ted Agres, "'Doing the Right Thing' to Ensure Food Safety: Incorporate Food Safety into all Aspects of Your Business or Risk Becoming a Target of FDA's New Enforcement Powers", Food Quality and Safety Magazine, June/July 2014. See also Acheson, "FDA FSMA Facility Suspension Power", *supra* note 41.
[81] See Jessica Dye, "Experts Predict More Criminal Scrutiny for Food Safety in 2014", Reuters Legal, 26 December 2013.

The third major component of the FSMA pertains to imported foods.[82] The law requires importers to verify that their suppliers are in compliance with the US food safety system, and authorizes FDA to establish programs requiring certifications for certain foods[83] and recognizing third party audits.[84] These provisions impose significant responsibility on private importers and auditors – rather than the FDA – to detect and prevent contamination of imported foods. Imports make up an increasing proportion of the US food supply, so this allocation of authority establishes in public law a significant role for the private sector in policing and ensuring food safety.

d. Funding

A final important component of the law pertains to funding. During deliberations, how to fund the law was a significant issue of concern. The House version had included facilities' registration fees while the Senate version did not. It was expected the fees would be included in a final version when the bill was finalized by a joint conference committee of the House and Senate.[85] Due to the delay in passing the Senate bill, the final law included no provisions to guarantee funding for FDA's increased activities. Consequently, FDA must annually request (and justify) a budget as part of the appropriations process.

III. Implications

As a historic revision of US food safety law,[86] the FSMA grants the FDA broad new powers. Yet closer examination reveals that, though some significant changes occur, in many ways the law repeats or fails to address past public regulatory failures, and does not fundamentally restructure the roles and relationships between actors in the broader food safety governance network.

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[82] FSMA, *supra* note 7, § 301 *et sqq*.
[83] FSMA, *supra* note 7, § 303
[84] FSMA, *supra* note 7, § 307
[85] See Helena Bottemiller, "Senate Holds Hearing on Food Safety Reform", Food Safety News, 23 October 2009, stating "many experts expect that the house's fee provision will survive conference if the senate does not add a fee provision to help fund the bill, but it is an issue that will be watched very closely."
[86] Helena Bottemiller, "Historic Food Safety Bill Signed Into Law", Food Safety News, 5 January 2011.

Disaggregating and closely examining the various actors in the context of the FSMA shows how the law changes the roles and relationships between regulators, the regulated industry, and other stakeholders.

1. Government

a. Hybridizing Authorities

The FSMA gives FDA power to mandate new food safety standards and an expanded toolkit for enforcing them. Yet the HACCP-like preventive controls and new import programs also assign significant new responsibility to manufacturers, importers and auditors for ensuring food safety. Additionally, the limited funding and small-scale exemptions will necessitate relying on states to carry out inspections and assist in outbreak investigations.

The FDA has historically contracted with states to carry out significant portions of inspection and oversight of facilities, as well as coordinating on development and adoption of the Food Code. Though altered, the FSMA does not profoundly restructure the relationships between Federal and State agencies. The new role for importers and third party auditors is, however, a significant new relationship that will require the FDA to develop effective systems for coordinating with these actors.

Hybridization of public and private regulation has occurred in other countries[87] and industries.[88] This parallels broader processes in governance, where public agents are increasingly expected to manage complex networks in order to achieve government objectives and deliver services.[89] In addition to understanding and enforcing food safety best practices, the FDA must now develop

[87] See, e.g., Marian Garcia Martinez et al., "Co-regulation as a possible model for food safety governance: Opportunities for public–private partnerships," 32 *Food Policy* (2007), 299 *et sqq.*, Paul Verbruggen and Tetty Havinga, "Food Safety Meta-controls in the Netherlands", in this Special Issue.

[88] For example, forestry has seen the emergence of private standard that are increasingly mandatory due to public adoption of the standards. Errol Meidinger, "The Administrative Law of Global Private-Public Regulation: the Case of Forestry," 17 *European Journal of International Law* (2006) 47 *et sqq*.

[89] Eva Sorensen and Jacob Torfing, "Making governance networks effective and democratic through metagovernance," 87 *Public Administration* (2009) 234 *et sqq*.

expertise in understanding auditing practices and develop strategies for coordinating and partnering with private auditors and importers for the effective oversight of imported foods. This is potentially problematic, given that the coordination and oversight of states by FDA has been criticized as ineffectual[90] and the Government Accountability Office has recently called for improving overall coordination of food safety systems.[91] Further, the states' role under FSMA occurs at a time when states inspection capacities are being reduced by funding cuts[92] and no money is being provided to assist importers or third party auditors. This means the FDA has a daunting task.

b. Hampered by Lack of Funding and Expertise

Interviews with produce industry and food manufacturers also raised concerns that FDA has limited experience regarding the realities of the production processes and business practices that ensure the safety of products. Industry had been developing and extensively implementing standards for production and processing of food. The agency has experience with these systems, through work it has done developing HACCP programs for juice[93] and seafood[94] and GAP guides for the produce industry. However, the FSMA imposes responsibility to regulate a far broader and more diverse set of products within a single cohesive set of regulations. Given FDA's limited experience with only single-product regulations, it is a significant challenge for the agency to develop and implement a set of regulations that are general enough to apply to all foods, yet not so vague that they will be inconsistently enforced.

These challenges are further complicated by Congress's failure to fund the law through facilities fees. Rather than being able to rely on a secure source of funding for operations, the agency must

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[90] See OIG oversight reports, *supra* note 75.
[91] Government Accountability Office, Federal Food Safety Oversight: Additional Actions needed to improve planning and collaboration, GAO-15-180, Dec. 2014.
[92] http://www.foodquality.com/details/article/6166181/Staffing_Reductions_Curtail_Prevention_Investigation_of_Foodborne_Illness_Outbre.html
[93] 21 C.F.R. § 120.1 (2014)
[94] 21 C.F.R. § 123.6 (2014)

pursue funding through the normal appropriations process. Consequently, as the agency attempts to write and enforce the regulations, stakeholders retain a key leverage point for holding the agency accountable for actions stakeholders are unhappy with.[95]

c. Implications for FDA

Between the partnering mandates, lack of funding, and lack of expertise, this is a law that FDA cannot implement unilaterally. The agency needs other members of the food safety governance network to subscribe to the agency's coordinating efforts. The FDA has been repositioned as a network manager that attempts to coordinate a dispersed network of actors with variable powers and expertise. Through its clout as a federal agency, the FDA retains significant power to regulate, but that power is now exercised through a more dispersed and collaborative set of relationships with other regulators, regulated entities and stakeholders.

Scholars have argued for the promise of positioning regulatory agencies as co-regulators and harnessing the power of private regulation.[96] Under the FSMA, the FDA is severely resource constrained and subject to traditional administrative law mechanisms designed to hold the agency accountable to stakeholders.[97] Added to this is the agency's historically ineffective coordination of the simpler network of federal and state regulators. The FSMA clearly puts a strain on FDA's

[95] See e.g. *Examining the Implementation of the Food Safety Modernization Act, before the H. Comm. on Energy and Commerce, Subcomm. on Health*, 113th Congress (February 5, 2014).

[96] Tacy Katherine Hass, "New Governance: Can User-Promulgated Certification Schemes Provides Safer, Higher Quality Food?", 68 *Food and Drug Law Journal* (2013) 77 *et sqq.*; Jason Solomon, "New governance, preemptive self-regulation, and the blurring of boundaries in regulatory theory and practice," *Wisconsin Law Review* (2010) 591 *et sqq.*; Lesley K. McAllister, "Harnessing Private Regulation," *U-C Davis Legal Studies Research Paper* (2013).

[97] For instance, the agency must conduct rulemaking through the traditional "ossified" notice and comment process, rather a more flexible process such as negotiated rulemaking whereby the agency convenes the stakeholder groups to negotiate a set of rules. Jody Freeman, "Collaborative governance in the administrative state," 45 *UCLA Law Revew* (1997) 1 *et sqq.*.

expertise and capacity to act as network coordinators, and the agency's success in its new role will necessitate careful future assessment from a variety of angles.[98]

2. Industry

This examination of the FSMA also necessitates examination of how public regulation may be reshaping private regulations.[99] For industry on the whole, the provisions of the law do alter some actors' roles and responsibilities in the governance of food safety, particularly relative to the FDA. However, the law leaves in-tack portions of the private regulatory regime so that, in some ways, there is little change in the relative authorities and responsibilities within industry. While the law adds responsibilities for many smaller and midsized producers, for those selling to major retailers the law only minimally changes the obligations relative to private standards. Nor do any provisions redistribute the power of retailers and buyers, so that anyone wishing to sell to these buyers must still comply with stringent food safety standards that exceed the floor established by the FSMA.

a. Food Producers

For food producers, the new provisions have varied effects depending on their previous roles. Many growers and manufacturers already are subject to private governance regimes that impose stringent food safety standards and auditing requirements, such as the GFSI benchmarked schemes for retailers and the LGMA standards for California and Arizona leafy greens growers. For these producers, the implications of the changes will depend in large part how much the FDA's rules diverge from current industry practices. The adoption of HARPC, rather than HACCP, means that US food safety regulations could in some ways diverge from global standards. On the whole, industry informants expect this divergence from globally accepted terminology and practices to make

[98] See, e.g., Sorensen and Torfing, *supra* note 89; Erik-Hans Klijn, Bram Steijn & Jurian Edelenbos, "The impact of network management on outcomes in governance networks", 88 *Public Administration* (2010) for discussions of how network managers might be evaluated.
[99] Lars H. Gulbrandsen, "Dynamic governance interactions: Evolutionary effects of state responses to non-state certification programs," 8 *Regulation & Governance* (2014) 74 *et sqq.*

compliance more complex for globalized food companies and complicate FDA's efforts at enforcement when dealing with companies in foreign countries. If this occurs, the law has the potential to simply add to the regulatory universe and may not help achieve resolution and harmonization to address the issues of conflict and rule-proliferation that these producers already face.

For many others, these are significant new requirements that, while bringing them up to speed with what others in the industry have been doing, will require significant education and investment in production processes.[100] The FDA initiated coordinated education with academics, states, and industry to reach this segment and ensure they understand and are in compliance with the new requirements. Most prominently, FDA has funded the Produce Safety Alliance and the Preventive Controls Alliance to develop and deliver educational curricula. The funding of these education efforts represents another example of how the complex governance networks are imposing an increased stakeholder coordination role on the FDA.

b. Exempt Producers

There are, in addition, a set of exempt producers and manufacturers. Despite a hard fought battle to have certain farms and small food manufacturers exempt from FDA's standards, one concern that has been raised by some advocates is that the marketplace will nonetheless impose private or public standards on small producers and force them to incur the high costs of audits if they want access to mid- or large-scale markets. This suggests that the power of retailers and buyers essentially moots out the power of the federal government to create "scale appropriate" regulation. Though federal regulations may override private regulation, private regulation can also preclude federal policy efforts, putting the two regulatory systems in a rather heterarchical status

[100] The importance of education for successful implementation of self-regulatory programs is key. Martinez et al., *supra* note 87 at 308.

relationship vis-à-vis one another. This pattern of private regulation precluding or preempting public regulation is not remarkably new.

c. Buyers

The implementation of the FSMA also resurrects a recurring discussion regarding who is ultimately responsible for food safety. As mentioned above, US retailers have relatively limited liability in the event of a food safety outbreak. However, they are often in the most powerful position to enforce (or undermine) food safety practices because their purchasing decisions affect the extent to which producers can and will invest in food safety. This issue has generated industry discussions of whether food safety is the responsibility of individual producers, or if retailers and major buyers must change their buying practices, or if universal, public regulation would solve food safety failures.[101] Currently, the FSMA puts responsibility on food producers and assigns enforcement authority to FDA, states, and importers, leaving retailers relatively unaccountable for ensuring food safety.

d. Third Party Auditors

Many audits are carried out by third party auditors because they are ostensibly independent and conflict-of-interest free. However, scholars have questioned the true independence of these audits[102] and many companies choose to use internal auditors for evaluating suppliers rather than or in addition to relying on third parties. The issue is one of accountability – as Busch asks, "Who will guard the guards?"[103] For imported foods, the answer now is that FDA will take on the role of

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[101] See Discussion, *Supra* Section II.1. See also Jim Prevor, "Buyer Led Food Safety Initiative Recap", *supra* note 18, Jim Prevor, "The Cantaloupe Crisis: The Truth That Dare Not Speak Its Name: The Priority can be Safe or the Priority can be Local, but it cannot be Both", Perishable Pundit, available on the Internet at: <http://www.perishablepundit.com/index.php?date=10/04/2011&pundit=1> (last accessed on 13 October 2014).

[102] Scholars have questioned this independence. See Maki Hatanaka And Lawrence Busch, "Third-Party Certification In The Global Agrifood System: An Objective Or Socially Mediated Governance Mechanism?" 48 *Sociologia Ruralis* (2008) , pp. 73 *et sqq*.

[103] Lawrence Busch & Carmen Bain, "New! Improved? The Transformation of the Global Agrifood System," 69 *Rural Sociology* (2004) 321 *et sqq*.

guarding the guards. For domestic production, private auditors will remain subject to the systems of private accreditation and oversight that preceded the FSMA. This partial adoption of the private inspection system in a limited way recognizes the potential legitimacy of private actors as inspectors and regulators, so long as they remain subject to systems of government oversight.

3. Civil Society

Remarkably, despite civil society's significant role in the enactment of the FSMA, the analysis does not suggest there has been a radical restructuring of roles. Clearly the consumer groups influenced the bill, but their power was limited until industry was willing to support and work with consumer groups on the legislation. While the battle over exemptions revealed a fracture between the food advocacy civil society organizations that one might expect to have common interests, it is also normal for civil society movements to have internal conflicts and rifts.[104] The possible importance here is that the FSMA battles highlighted the importance of including the alternative groups. Though sustainable and alternative organizations have had past policy advocacy successes, several interviews noted that the FSMA conflicts significantly elevated these organizations' status as a legitimate and distinct perspective.

IV. Conclusions

Private regulatory regimes in the United States emerged to fill in gaps and breakdowns that were resulting from an ineffectual domestic regulatory agency and to manage the risks in global food supply chains. This is not to say government agencies were absent; the FDA did what it could under the FDCA while other state and federal agencies were partnering with various sectors to govern

[104] See, e.g., Robert Gottlieb, *Forcing the spring: The transformation of the American environmental movement* (Island Press: Washington DC, 2005) for a discussion of the diverse roots and conflicts that have played out in the environmental movement in the United States.

food safety. However the plurality of policies was forcing producers and manufacturers to comply with multiple, stringent standards that were becoming increasingly costly and difficult, and efforts to harmonize the regimes were largely ineffectual. At the same time, uneven adoption and enforcement failures were allowing frequent outbreaks to occur, creating a perception of eroding consumer trust in food companies and the US food supply.

In the late 2000s, consensus emerged among the major stakeholders that federal legislation would be beneficial. Following a typical pattern of the policy cycle, [105] it was not clear until the last possible moment that food safety legislation could outcompete other agenda items to successfully be passed, nor what provisions would be finally included. Consumer groups took advantage of the democratic House, Senate and President, combined with the ongoing outbreaks, to force open a policy window and bring food safety reform onto the Congressional agenda. The policy alternatives that were considered had been developed and tested by subsets of stakeholders in other venues, such as the LGMA and GFSI. As a result of the outcomes seen in those venues, stakeholders hotly contested how broadly regulations should apply and the appropriate roles of state and private regulators in overseeing and enforcing food safety.

Ultimately, what was produced was not necessarily a rational law, but rather a series of compromises on previously tested policy alternatives that politically effective stakeholders agreed they could live with. The FSMA both expands FDA domestic and import authority and elevates the role of private regulators and industry. For FDA regulators, the law means trying to walk a line between independence and collaboration, while being responsive to a variety of conflicted stakeholders. For industry trying to manage global systems, the law could help by setting a floor for all producers but create increasing regulatory complexity. And for the private regulators, the law holds potential to increase their legitimacy as effective guards of food safety.

[105] Kingdon, *Agendas, Alternatives and Public Policies*, *supra* note 13.

With the enactment of the FSMA, the United States has moved towards an increasingly integrated public-private regulatory system. The next phases, rulemaking and implementation, will constitute another venue of interactions. The outputs will clarify just what roles stakeholders might play and possibly shift the impacts of the different regulatory regimes. This may catalyze contests and policy cycles in multiple other venues, including potential court challenges to FDA's decisions, as well as shifts in GFSI schemes and rewriting of the USDA and state-level regulations and enforcement. With the shift to the increasingly complex networks of governance, on-going research will be needed into the dynamic and continuous processes that now shape food safety governance in the United States.

Chapter 3: Food Safety Governance in the Shadow of Overlapping Networks: Implementing the U.S. Food Safety Modernization Act

Abstract

Using the Food Safety Modernization Act (FSMA) as a case study, this paper examines the legitimacy and accountability of multiple, overlapping policy networks engaged in food safety governance in the United States. The paper focuses on the FSMA because it places the Food and Drug Administration in a regulatory position where it must coordinate and partner with these overlapping regulatory networks, but subject to traditional administrative law mechanisms of legitimacy and accountability. The paper argues that the individual networks display divergent systems of producing legitimacy and accountability, which makes the FDA's obligation to coordinate and harmonize these networks more difficult. Further, the proliferation of multiple, overlapping networks challenges the capacity of some stakeholders to meaningfully participate in governance. The paper concludes by suggesting that achieving normative values such as legitimacy and accountability is made more difficult by the proliferation of regulatory networks.

Introduction: FSMA as New Governance & the Proliferation of Food Safety Policy Networks

The Food Safety Modernization Act and Contemporary Governance

The Food Safety Modernization Act is an example of efforts to incorporate into law experimentalist, collaborative governance processes that take advantage of the emergence and competition of diverse problem-solving approaches (Hass, 2013; Sabel & Simon, 2011; Solomon, 2010). This effort falls under the rubric of 'New Governance', which includes efforts to regulate through practices such as experimentalist regulation (Sabel & Simon, 2011), responsive regulation (Braithwaite, 2011; Parker, 2013), and collaborative governance (Bingham, 2010; Freeman, 1997), among many

others. Though there is significant intellectual variation across these approaches, they share an effort to re-orient administrative law studies and practices "toward a new model of collaborative, multi-party, multi-level, adaptive, problem-solving." (Karkkainen, 2004, p. 473). In its idealized form, 'new governance' enables participation by diverse stakeholders in a flexible, non-coercive, adaptable, regulatory process that creates dynamic learning through implementation (Lobel, 2004). The turn towards 'new governance' is a response to the failures of 'old governance' characterized by command and control regulation (Karkkainen, 2004; Lobel, 2004). The ossification of rulemaking processes and consequent reticence of regulators to revisit rules as conditions change is a well-documented problem (McGarity, 1992; Pierce, 2012). Impulses to constrain agency discretion have been particularly harmful, hampering agencies' ability to experiment with more collaborative approaches (Freeman, 1997).

Several factors make the FSMA an example of new governance. The law adopts food safety practices already used in public, public-private, and private regulatory networks,[106] including Hazard Analysis and Critical Control Points (HACCP) systems for food manufacturers, Good Agricultural Practices (GAPs) for produce growers, and oversight through private, third party auditors. The FSMA directs the Food and Drug Administration (FDA) to develop HACCP-like standards for food

[106] The concept of networks is used in an array of ways (Bevir & Richards, 2009; Borzel, 1998; Rhodes, 2006). This paper uses networks as a heuristic tool for organizing the actors and relationships in various policy arenas, and thus uses the concept as a generic term to qualitatively analyze inter-organizational relations. However, it relies heavily on the idea that policy networks are self-organizing networks of inter-dependent individuals, who form the networks in order to exchange resources and negotiate to reach consensuses. As described by Bevir and Richards (2009), these networks self-organize because "lack of legitimacy, complexity of policy processes, and the multitude of institutions concerned, reduces the state to being only one of many actors. Other institutions are, to a great extent, autonomous; they are self-governing. The state steers at a distance."(Bevir & Richards, 2009, p. 6). In short, as used here, 'regulatory networks' refers to the concept that inter-organizations networks form in order to achieve regulation of peoples' behavior. These networks can form around the state and can play a critical role in shaping state policy and enabling the state to steer at a distance, but they can also self-organize in relation to other powerful actors, and so may or may not include the state.

It is not used here in the Latourian sense common in the sociology of agrifood governance literature (Busch & Juska, 1997; Loconto & Busch, 2010; Stuart, 2010) , which emphasizes that networks consist of overlapping networks of networks, include both human actors and non-human actants, and are composed of both entities and relationships.

manufacturing, and GAP-like standards for production of fresh produce. The FSMA also directs the FDA to develop a scheme for partnering with importers, third party auditors and foreign governments to improve oversight of imported food. In implementation, the FDA is expected to develop regulations that are risk-based and scale-appropriate to accommodate the diverse array of food products and manufacturing practices. Enforcement is to be risk-based and flexible, and the FDA is to partner with states and private actors to achieve effective oversight of food safety. Thus, building on self-regulatory efforts of industry, the law assigns significant responsibility to private actors for overseeing and ensuring the safety of food and requires the FDA to act as a collaborator rather than an authoritarian regulator (Hass, 2013; Sabel & Simon, 2011; Solomon, 2010). There is considerable enthusiasm for the potential of the FSMA to achieve a more flexible, responsive, dynamic regulatory system (Fagotto, 2010; Hass, 2013; Strauss, 2011; Taylor, 2014).

Governance in many countries is increasingly conducted by proliferating, self-organized regulatory networks composed of all manner of public and private social-political actors (Kooiman, 2003). In a number of policy domains, there has been a significant proliferation of networks that govern through standards and auditing regimes that are written and enforced by a variety of public, public-private, and private actors at local, regional, national and transnational scales (Abbott & Snidal, 2009). These patterns of overlapping governance regimes are prompting scholars to explore how regulatory processes and actors' roles and capacities are changing as the regimes increasingly collide and intersect (Havinga, Waarden, & Casey, 2015; Marsden, Lee, Flynn, & Thankappan, 2010). In this context, the FDA's mandate does not just require adopting flexible, responsive regulatory policies and developing collaborative relationships with regulated entities and other regulators. The agency also must regulate within proliferating policy networks that are reshaping the agency's regulatory roles and the capacities of stakeholders to participate in governance.

Two pervasive problems challenge contemporary overlapping public-private governance networks: legitimacy and accountability (Black, 2008; Fuchs, Kalfagianni, & Havinga, 2011; Stewart, 2003).

Legitimacy – or the acceptance of rules as appropriate and just - may be evaluated as a concept that is subject to actors' construction and contestation (Bernstein & Cashore, 2007; Bernstein, 2011), or it can be judged according to democratic normative standards, such as participation, transparency and accountability (Fuchs et al., 2011). The issue of accountability encompasses to whom are regulators accountable, for what, and how are they held accountable (Mashaw, 2005). Anxieties over the legitimacy and accountability of regulatory activities have existed for decades (Mashaw, 2005; Stewart, 2003). However, new complexities are arguably emerging as regulatory regimes proliferate.

Overview

This paper examines the perceived legitimacy and accountability of emerging food safety governance in the U.S., with a particular focus on the FDA's attempts to regulate within an increasingly complex regulatory landscape. Using the criteria of participation, transparency and accountability, this paper compares the ways in which different food safety stakeholders in the U.S. characterize three overlapping regulatory networks: the Food Safety Modernization Act network, the western Leafy Greens Marketing Agreement network, and the Global Food Safety Initiative network. Not surprisingly, the analysis shows the networks vary in their systems of legitimacy and accountability, with resultant variance in actors' perceptions regarding the legitimacy and accountability of the networks' regulatory activities. This raises a number of challenges for the FDA as it attempts to incorporate and coordinate with these regulatory networks. These include potentials for regulatory over-burdening and conflicts that undermine public policy efforts to balance competing demands. Finally, the paper concludes by arguing that the emerging global food safety system, composed of local and national food safety systems, transnational private systems, and supra-national systems such as the World Trade Organization and Codex Alimentarius, undermines the efforts of individual networks' for legitimacy and accountability. It thus raises

questions about the implications of governing through overlapping, heterarchical networks and the need for more research into the disparate outcomes and aggregate impacts of this regulatory path.

Design and Methods

The FSMA was a major revision to the U.S. federal food safety regulatory system, setting the U.S. further down the path of co-regulation with private regulatory networks. A case study examining the overlaps between federal regulation and related food safety regulatory networks allows examination of the consequences of the interplay between multiple, overlapping regulatory networks. The research design explores actors' characterization of the structure and processes of these regulatory networks.

The primary data for the research came from 37 semi-structured interviews with staff in industry and civil society organizations, federal and state regulators, congressional staff, food safety and regulatory compliance lawyers and academics, which were conducted between November 2013 and September 2014. Initial interviewees were identified based on preliminary research of who the major participants were in the enactment and implementation of the law. Further interviewees were identified and contacted through attending industry and consumer food policy conferences, which were also used as observational opportunities for better understanding the issues and discourses of stakeholder groups. Additional interviewees were identified using a snowball method by asking interviewees about their important partners and asking about stakeholders with whom they disagreed. This last question was meant to identify opposing views and ensure consideration of the full range of opinions. Interviewees were predominantly actors closely involved in policy making; thus some non-policy perspectives may not be fully included.

Interviews were recorded, transcribed and coded. Coding variables were developed deductively based on Marsh and Smith's conceptual framework of policy networks and policy change, which was modified to examine policy making in multiple, overlapping networks (Marsh & Smith, 2000;

Toke & Marsh, 2003). Additional codes were added inductively as new concepts emerged in the analysis.

Major coding categories included the venues of the policy networks, the structures of the networks, actor categories, actors' traits, actors' actions, characterizations of the process, and outcomes and impacts. The venue codes were the FDA's implementation, the GFSI network, and the LGMA network. Structural codes addressed the rules of participation, such as who may participate and how. Actor categories included consumer organizations, alternative agrifood organizations, the FDA, state/local regulators, and sectors of the food industry including but not limited to representatives of leafy greens and fresh produce growers, manufacturers, and retailers. Codes about actors' traits covered their strategic interests, resources, authority, and knowledge. Actors' actions were activities such as lobbying/advocacy, blocking/inaction, assuring or building trust, and learning. Codes about actors' characterizations of the processes included transparency, inclusiveness, difficult or easy, and speed. Finally, outcomes and impacts included policy choices, accountability, trust, conflicting or confusing policies, feasibility, and food safety. The data were analyzed in NVivo by cross-tabulating the seven categories so that I could ask questions such as what were different actor categories saying about outcomes in each of the venues?

Secondary materials, such as comments during the rulemaking process, media coverage, and public relations releases were also reviewed (but not coded and analyzed). This added additional understanding to the analysis of the interviews.

I. Food Safety Networks

In this paper, the analysis of food safety governance networks proceeds by describing the substantive issue that catalyzed the creation of the regulatory network. Then the analysis examines how well the respective networks are able to achieve legitimacy and accountability in the eyes of included and excluded stakeholders. The analysis then assesses how those procedural mechanisms

impact the regulatory capacity of each network to address the foundational issues that motivated its creation in the first place.

A. The FSMA Rulemaking

As a result of the enactment of the Food Safety Modernization Act, the FDA undertook notice and comment rulemaking to update U.S. food safety regulations.[107] The HACCP- and GAP-like standards and requirements to partner with states, other nations and private regulators force the FDA to entrust responsibilities for food safety to a number of other actors. Together with the provisions exempting certain small businesses and prohibiting conflicts with the National Organic Program and federal conservation programs, the law required the FDA to develop universally applicable regulations that are flexible with respect to diverse scales of enterprises and diverse types of food production.

The FDA must undertake rulemaking and implementation subject to administrative law constraints as they have evolved to exist at the beginning of the 21st century. These constraints include requirements for notice and comment rulemaking meant to ensure transparency and participation for stakeholders and mechanisms for holding agencies accountable to Congress, the executive branch and judiciary. Accountability mechanisms include Congressional oversight and appropriations, submission to the White House Office of Management and Budget for cost benefit analysis and coordination with other federal agencies, and judicial review of agency action.

Processes of Legitimacy and Accountability

In developing the regulations, the FDA undertook an extensive engagement process. Before issuing proposed regulations, the FDA solicited initial input on the regulations through preliminary requests for comments and pre-rulemaking hearings. In addition to the legally required notice and

[107] Supporters of the bill included major trade associations representing food businesses, a coalition of consumer groups and the FDA itself. The bill was opposed by alternative food systems advocates, coordinated by the National Sustainable Agriculture Coalition (NSAC).

comment procedure, FDA held on-the-record hearings for oral testimony and numerous listening sessions throughout the country with many different types of stakeholders – from small farmers to major commodity growers, food manufacturers, and the brewers association. The agency also held regular meetings with industry and consumer groups, state officials and alternative agriculture organizations. These activities provided an opportunity for the FDA to clarify their thinking for stakeholders and to receive extensive feedback on stakeholders' concerns regarding potential regulatory impacts.

Interviewees described stakeholder buy-in to the rules as important for gaining their support in implementation, particularly because the law assigns significant illness prevention responsibility to industry. While the notice and comments procedure was typical of rulemaking, the extent of the outreach through visits, listening sessions and one-on-one meetings was characterized as exceptional by many interviewees. A number of interviewees noted this level of stakeholder engagement was propelled by the magnitude of regulatory change and because manufacturers and growers had knowledge of the realities of production that the FDA did not. Interviewees across sectors noted that the transparency and participation would contribute to achieving regulations that are perceived as workable and responsive to the practices and needs of industry, including large and small, conventional and alternative.

A number of industry interviewees also noted that manufacturers and buyers can act as partners in implementation. Industry had valuable expertise for executing a risk-based enforcement regime, including data on which facilities represent what kinds of risks. The systems of private audits were also described as a way to help producers achieve compliance and provide oversight where the FDA and state regulators may not have the capacity.

While the FDA was mired in notice and comment proceedings, it was also pulled in divergent directions by administrative accountability mechanisms. First, stakeholders reached out to members of Congress to exercise power over the agency through Congress' funding powers,

oversight hearings, and letter writing. Second, the agency was also under a court order to complete the rule making by the end of 2015. This was the result of a settlement with a consumer advocacy group that sued the FDA for failing to meet statutory deadlines. Interviewees in industry and government criticized this maneuver for forcing the agency to act quickly, rather than allowing it time to get the regulations right.

Finally, the FDA's delays were in part due to review by the Office of Management and Budget (OMB). By statute and executive order, significant federal regulations must undergo review by OMB, which is coordinated by the Office of Information and Regulatory Affairs (OIRA). This involves a cost-benefit analysis of the proposed regulations and coordinated review by other federal agencies (Copeland, 2006; Sunstein, 2012). In this case, review took over a year and then eliminated a number of proposed provisions, including product testing and environmental monitoring. Industry and consumers groups considered the eliminations to have significantly watered down the proposed regulations.

Challenges and Issues

Three key issues emerged in the rulemaking that are linked to the FDA's mandate to develop a flexible, risk-based regulatory regime that intersects with other regulatory regimes. The first is what comprehensive but flexible regulations should look like for incredibly diverse types and scales of food operations. This is closely tied to the second and third issues, which are how to balance risks and how to regulate with scientific uncertainty and change.

The first issue was how to make the rules sufficiently flexible to match the diversity in types and scales of food production that exist in the U.S. food system. The disparate concerns in the following examples demonstrate the challenges of creating universal but flexible rules. At one point, a high profile controversy exploded over whether spent grain from brewing, which is commonly diverted to animal feed, would be subject to the HARPC requirements being developed for animal feed. The dairy industry was concerned about how HARPC would integrate with the proscriptive regulations

already enforced under the Federal Pasteurized Milk Ordinance (PMO). The produce industry and alternative agriculture raised issues with defining the divide between raising raw agricultural commodities (RAC)108 (subject to the produce standards) and processing commodities (subject to HARPC). There was also an issue of whether FDA should write one comprehensive rule for produce or commodity specific rules and how the FDA should define revenue for purposes of qualifying for exemptions. There was also significant conflict over how the proposed regulation would integrate with rules under the National Organic Program. Interviewees across sectors, including industry and alternative food organizations, noted that regulations cannot be one-size-fits-all. This sampling of different stakeholders shows just how much diversity the FDA would have to address in trying to write any set of comprehensive but implementable regulations.

A second issue was how to regulate for risk. Consumer groups generally advocated for more stringent, restrictive standards, which are more precautionary of human and animal health, while food industry groups and sustainable agriculture groups advocated for more flexible, permissive standards. These positions were based on different definitions of the risk or potential problem at issue, differences over what level of risk to tolerate balanced against the costs of controlling the risk, and how to best control a risk.

Making regulatory decisions was further complicated by the third issue of significant scientific uncertainty, which made it difficult to accurately assess potential tradeoffs. Further, the science evolves rapidly, so there was tension in how fast to move on finalizing regulations. A related tension was whether to formalize requirements in legally binding rules or leave standards to be written in guidance documents that are more easily revised but have less legal force.

The provision on the use of raw manure in fresh produce production illustrates these issues. Based on limited science, the FDA initially proposed requiring a nine month interval between application

[108] In the regulation, 'raw agricultural commodities' refers to fruits, vegetables and nuts that are meant to be consumed raw and are not intended for further processing. It does not refer to foods such as grains or oilseeds.

of raw manure and harvesting of produce. Consumer groups supported this as precautionary of preventing microbial contamination of food, while sustainable agriculture proponents opposed the proposal for being based on inadequate science and conflicting with the organic standards. To them, the greater risk to be concerned with was the risks to human health and the environment from chemically intensive agriculture. Some comments also argued that diversified, rotational crops and grazing posed less risk of microbial contamination because it encourages faster microbe die-off. There is not extensive scientific evidence for estimating how fast microbes die off, what conditions cause variations in die off rates, or how levels of microbial presence translate into human health risks.

To address this, the FDA proposed to defer decision making until it obtained more research and conducted a more thorough risk assessment. But manure was just one issue; other conflicts included, but were not limited to, how to identify and control microbial contamination in agricultural water, defining the scale at which to exempt businesses from regulation and whether scale is even an appropriate metric for assessing risk, and how to address risks occurring from different marketing channels. The FDA could not defer every decision until there is more science and more certainty, so the issue became how (if at all) the FDA could be responsive to variable risk tolerances and changing science?

The problem is that oversight systems that evolved to ensure transparency and accountability of public regulation are also 'ossifying' the process. The FDA must engage in resource intensive, time consuming activities to survive review by Congress, the courts, and the White House, which delays rule making and makes agencies reluctant to revisit or initiate new rulemaking (McGarity, 1992). Consequently, any final rules are likely to be inflexible to changes in science, manufacturing and production practices, and social norms.

There is debate about whether the ossification of rulemaking is a real concern (Pierce, 2012; Yackee & Yackee, 2012). Interviewees raised the FDA's recent eight year rule-making process to establish

standards for production of shell eggs as justification of fears about the FDA's ability to revise the FSMA regulations in the future. These fears play into a desire that the FDA incorporate more flexible, responsive regulatory mechanisms for modifying the rules once it has established a floor of robust requirements. A number of stakeholders argued for having numerical standards and requirements where science is unsettled put into guidance documents, rather than including them in the final rule. While guidance documents are more flexible, they are also not legally enforceable and there are no binding requirements for inclusion of stakeholders in the development of the guidance documents.

Another concern that needed to be addressed is how to develop regulations that are flexible to the diversity of scales and types of production and marketing. Part of the concern was that regulations would be inflexible and stymie marketing innovations. For instance, opposition to the FDA's proposed definitions of "farm" and "facilities" occurred because the distinction was going to make activities like aggregating produce from multiple farms subject to inappropriately complex HARPC rules. Another concern was that risks for certain commodities – especially leafy greens – were already better understood, so interviewees expected commodity-specific guidelines would be necessary. There was a sense that no comprehensive rule was going to get to the level of detail necessary for each commodity.

Two approaches may help alleviate this concern. First, the FDA could develop tailored guidance for specific types and scales of production. One way to do this is to rely on and integrate with the more tailored, industry driven regulatory regimes that intersect with the FDA's authorities. Second, the FDA could allow for variances or alternatives to the regulations as written. Such mechanisms are, however, arguably a way that agencies evade rulemaking and its accompanying accountability mechanisms and political processes.

Summary: Process Perceived as Legitimate and Accountable, but Potentially Hampered by Ossification

Despite the delays and conflicts among stakeholders, the general consensus across different groups of interviewees was that the FDA's rulemaking process was productive. Food industry representatives, alternative food systems advocates and consumer groups all commented that the FDA had genuinely tried to engage stakeholders' and respond to their concerns. The FDA's explanations in preambles to the proposed rules, frequent meetings, and listening sessions have provided opportunity for stakeholders to understand *why* FDA has taken actions, even if they disagree with the actions. This is not to claim that influence was equitable across groups; indeed, research in other domains suggests that industry influence likely outweighs other stakeholder groups (Wagner, Barnes, & Peters, 2011). Nor will the FDA's efforts necessarily forestall further litigation or review by Congress and the White House. Nonetheless, there was remarkable consistency among stakeholder groups in their perceptions that the FDA had recognized them and attempted to respond to their concerns.

B. California & Arizona Leafy Greens Agreements Policy Networks

The leafy greens marketing agreements in California and Arizona were precipitated by the 2006 outbreak of E. coli in leafy greens, which was ultimately traced to a field of spinach in the Salinas Valley. The network solidified when Western Growers Association submitted a request to the California Department of Agriculture for a Leafy Greens Marketing Agreement (LGMA). This network initially consisted primarily of growers, processors, handlers, academics, and the California Department of Agriculture. Thus, though a public-private initiative, it was dominated by industry interests and largely failed to include any sector of civil society.

When establishing the LGMAs, the key concern was to rapidly rebuild trust in and demand for leafy greens and to achieve broad industry buy-in. Thus, issues of legitimacy to buyers and consumers

and legitimacy and accountability to leafy greens growers and handlers were important. The marketing agreement approach emerged as the fastest way to get a set of requirements in place that growers and handlers could be comfortable with, and it involved government in a manner that provided transparency and accountability that would build trust with consumers, buyers and the leafy greens industry.[109]

Processes of Legitimacy and Accountability to Industry, Buyers, Consumers

For the growers and handlers, the marketing agreement process provided a responsive, flexible, dynamic regulatory system. The industry got a regulatory structure that they are invested in and that can respond quickly to their evolving food safety needs. For example, the LGMAs adopted metrics for assessing whether or not a farm had taken effective steps for controlling food safety risks. Although previously existing GAP standards provided recommendations on what activities farms should undertake, the metrics were preferable for growers because they provide clear standards for measuring whether they had done what they needed to or not.

The structure also allows growers to respond to the state of the science when defining these metrics. Numerous interviewees emphasized using science to justify their decisions, but a problem exists where there is not clear science or the science changes rapidly. The benefit of the LGMA was that participants could be comfortable with making decisions based on unsettled science because the structure allows for rapid revisions when better science emerges.

Interviewees strongly emphasized that participation in the agreement would be voluntary. If someone disagrees with the science or metrics, they can choose not to participate. However, all the major buyers in the area signed on to the agreement. Consequently, anyone wanting to sell into the commercial markets served by those buyers must comply with requirements of the LGMA. Thus, for

[109] There were also two other food safety policies under consideration when the LGMA was created. One, there was a buyer led food safety initiative, which lacked grower support because of distrust of buyers' actual commitment to food safety. Second, there was a proposal from Sen. Florez for a state managed food safety program. This was not supported by the industry because it would be too slow to implement and wrested too much control from the industry for determining the most effective practices.

many, the standards are in operation not voluntary. This turned out to be problematic for a number of stakeholders that were not included in the initial formulating of the LGMA.

Industry interviewees also suggested the marketing agreement built legitimacy with buyers, both retailers and consumers, in a number of ways. The industry interviewees characterized the rule-making and enforcement as transparent and accountable because it was a government process. The marketing agreements also meant government auditors could be funded through an assessment. That way, individual growers were not directly paying their auditors, which bolstered the perceived independence of the enforcement system. This was important because privately audited programs have been criticized for having producers pay for their own audits, creating a perceived conflict of interest (Hatanaka & Busch, 2008).

Other Groups' Perspectives on Legitimacy and Accountability

Despite the strong buy-in from growers and handlers for the LGMAs, other affected groups expressed opposition to and frustration with the LGMAs. California conservation groups recognized that practices in the interest of food safety were forcing farmers to rip out riparian buffers and habitat that could harbor wildlife that might contaminate fields. These groups intervened in the policy network, and worked with the LGMAs to develop co-management practices for promoting food safety and conservation practices. Despite this success, comments to the FDA noted that some buyers continue to require practices exceeding the requirements of the LGMA which undermine efforts to restore conservation farming in much of California.

Advocates for small and alternative farmers continue to express feelings of frustration and exclusion from the process. For instance, one interviewee criticized the LGMA for tending to write standards that only work for the big industry and not worrying about the smaller businesses. Yet stakeholders who are in the network described the LGMA network being responsive to these concerns and working to produce a result that is 'doable' for them. As examples, they cited

development of co-management practices, inclusion of large organic firms as members of the LGMA board, and instances of small-farms that were successfully audited under the LGMA.

One apparent source of this difference of perception is a failure to distinguish between standards imposed by different regulatory bodies. There are news stories and anecdotes of the challenges small producers, particularly diversified producers, encounter when trying to achieve USDA GAP certification. Buyers are also known to impose standards beyond what is required by either the LGMA or GAPs programs, standards sometimes termed "super-metrics." In personal communications and observations, individuals would switch between discussing these regulatory regimes without noting they were talking about wholly different regimes. Comments from sustainable agriculture advocates to the FDA commented on the need for the FDA to recognize and incorporate co-management practices like those adopted by the LGMA, yet the LGMA continues to battle the perception that its metrics are incompatible with organic farming, for instance as indicated by the LGMA's blog post on 5/29/15 "Mythbuster: LGMA Metrics and Organic Production."

This disconnect was aggravated by strong industry opposition to the qualified exemptions for small farmers. A significant point of conflict in the FSMA enactment and a point often debated on industry forums such as PerishablePundit.com is whether small producers should be held to a different set of standards. The idea is usually rejected as unscientific and inappropriate for food safety, because pathogens do not care what size a farm is. Further, if selling to major retailers, an outbreak has the potential to damage the reputation of a commodity across the country, even if confined to a particular region or seller. Alternative advocates argue, meanwhile, that different processes are necessary for small farms because the types of risks they present are different. The apparent indifference to the disproportionate burden of standards on small farms feeds into the perception that standards such as the LGMA (and to some extent, the FDA's FSMA rules) are written by and for 'big agriculture.'

Summary: Perceived as Flexible and Responsive, Tainted by Continued Perceptions of Unequal Influence

The LGMA was expected to continue to operate as a scheme that will overlap with any regulatory activities of FDA because it is able to provide a more flexible regulatory scheme that can respond to evolving science and industry needs. To some extent, harmonization between the LGMA and the FSMA standards is emerging because the LGMA provided expertise for writing the produce rules and LGMA members are providing extensive feedback to the FDA on the proposed rules. Proponents of the LGMA, hoping to achieve harmonization and reduce regulatory burdens, want even greater consistency in order to achieve some level of partnership in implementation. However, perceptions linger that the LGMA was not responsive to alternative and sustainable agriculture. Experiences with industrialized agriculture and retailer-driven standards in California mobilized significant sustainable agriculture opposition to the FSMA. This resulted in exemptions and requirements that complicate the FDA's mandate to develop standards applicable to the full breadth of raw agricultural commodities produced and consumed in the U.S., are more flexible to greater diversity than the LGMA, and must appear legitimate and accountable to more stakeholders. This raises a tension regarding whether, and if so, how, the FDA can or should integrate the FSMA with the LGMA.

C. GFSI

Another major regulatory network was the Global Food Safety Initiative (GFSI), an organization established by a group of multi-national retailers. With globalized supply chains, these retailers needed a strong food safety system that could ensure food safety met legal standards in multiple countries and provide assurances of the safety of food being sourced from countries with weak regulatory systems (Fulponi, 2006; Hatanaka, Bain, & Busch, 2005). Prior to creation of the GFSI, retailers required suppliers to be certified to a number of separate food safety standards.

Recognizing suppliers were being subjected to numerous, mostly redundant audits that appeared to do little to improve food safety, the retailers created the GFSI. The organization established a set of standards for recognizing the equivalency of food safety audit schemes. For manufacturers and growers, being audited to a GFSI recognized standard should enable them to sell to any buyer who requires a GFSI audit, regardless of which audit organization they hire or to which standard they are audited. For global retailers and manufacturers, GFSI audits allow them to source from a wider spectrum of suppliers while ensuring a product meets regulatory standards in any country where they operate.

The mantra of GFSI is that producers can be "once certified, accepted everywhere" and so reduce the number of audits. While some manufacturers noted this allowed them to successfully reduce audits and re-deploy their resources to focus on safety innovations, there continues to be a proliferation of audits. Many buyers require their own standards on top of the GFSI standard, send their own auditors, or require government-backed audits such as the LGMA. The redundancy of GFSI and LGMA is currently unresolvable because the government standards are owned and audited by the same entity, contravening a core separation of authority required by the GFSI. It is not currently clear how certifications to the FSMA standards might fit into this universe, but there was concern that the FSMA standards and enforcement schemes could simply add to the redundancy and regulatory burden without achieving food safety improvements for companies already subject to other food safety schemes.

An example of redundancy problems was raised for produce. As a global trade-oriented organization, GFSI's standards ensure foods can be sold anywhere the retailers and manufacturers operate. To this end, GFSI addresses the non-regulation of pesticides in developing countries and enables the sale of produce in developed countries with differing pesticide standards. U.S. growers must comply with U.S. pesticide regulations, and so these GFSI requirements were perceived as inappropriate by the U.S. growers. Research that examines standard redundancies in other

countries and overlapping standards shows that too much redundancy can lead to only partial performance of the standards and selective decisions about which standard and accompanying marketing channel to adopt (Berman, 2013). On the other hand, other research has shown that strong government and civil society regimes overlapping with private regulation can enhance compliance (Toffel, Short, & Ouellet, 2015). This suggests redundancy is less the problem than how smoothly the public and private regulations are integrated.

Accountability and Legitimacy to the Public and Regulated Actors

Like other globalized and privatized systems, the GFSI is designed with a number of checks and balances to create accountability in the regime (Hatanaka & Busch, 2008; Lytton & McAllister, 2014). Auditors and standard owners (referred to as "scheme owners" in GFSI) must be separate entities, and the scheme owner authorizes auditors to conduct audits and certifications to their standards. GFSI places management responsibility on scheme owners to ensure the credibility of auditors and maintain the rigorousness of their standards. Auditors must have an independent accreditation that they conform to international auditing standards such as the ISO/IEC Guide 65. This multi-level oversight of manufacturers, auditors and scheme owners is meant to create trust in the safety of GFSI audited foods.

The GFSI also purports to make procedures transparent and open to stakeholders at multiple levels. As part of their scheme management responsibilities, scheme owners should engage in feedback and revision processes to maintain the currency of their standards and must establish procedures for complaints and appeals regarding auditing decisions.

Much of the work of GFSI is carried out by technical working groups. Any stakeholder can apply to be on a working group, though selections are made trying to achieve a mix of sector and geographic representation. The most well-represented entities in the GFSI technical working groups are retailers, major food manufacturers, standard owners, and auditor organizations. Interview subjects who participate in these GFSI technical working groups describe them as attempting to be

transparent and open. Participants also described a very deliberative, engaged process that is based in science.

Although all stakeholders are ostensibly welcome to participate, interviewees noted there were barriers limiting their inclusion. Resource constraints can preclude stakeholders from regularly attending meetings. Representatives must pay their own travel costs to attend the physical meetings of the working groups and are required to attend at least two out of three physical meetings per year. For resource-constrained organizations these travel costs become a barrier to attending and thus being a working group member. For others, it was not entirely clear how to participate or how to have an influence. For example, one organization expressed uncertainty about how or whether they would be able to participate in future guidance documents revisions. The same interviewee also mentioned thinking that certain actors within GFSI were representing their interests, and then after the fact finding that they were not. For stakeholders such as these, the perception was that they had limited success participating and getting their issues addressed by the GFSI standards, despite the GFSI's ostensibly open and transparent processes.

Accountability to Global Retailers' Interests

Consistent with other research into private standards organizations (Fuchs et al., 2011), the activities of the GFSI appear to primarily address the needs of the globalized board members. Strategic direction for the organization is set by a board of directors, which is composed mostly of retailers and multinational food manufacturers. The GFSI board identifies issues and defines scopes for technical working groups to address. The current issue raised most frequently by interviewees was the competency and consistency of auditors. Consumer group and audit sector interviewees recognized that recent outbreaks made it appear that auditors, who are paid by the companies they audit, appear to be more accountable to their clients than to end consumers. Auditors themselves were also suffering because they had to be accredited to a slightly different standard by each standard owner, which created redundancies for them. Further, entities being audited select their

auditors and would occasionally critique the competency of the auditor in order to contest the results of their audit. By establishing a harmonized standard for auditors, the members of the GFSI articulated that this would create transparency regarding what constitutes a competent auditor and a new layer of accountability that builds the perceived legitimacy of the GFSI scheme of private food safety governance.

Another example of GFSI activities pursuing the interests of global retailers was the Global Markets Working Group, which helps small companies and those from less-developed countries achieve compliance with GFSI schemes. Despite objections from the produce industry that this creates a two tier system that undermines food safety, this program is beneficial to the global buyers who gain greater access to a broader, and thus more flexible, source of suppliers.

Summary: Problematically Redundant, Ineffectual Participation and Insufficient Transparency

In short, the focus of GFSI's activities has been on the primary concerns of the audit industry and the retailers, which are to build trust in the system and achieve a flexible global supply chain. Though other stakeholders are ostensibly included, participation was a challenge for stakeholders who did not have the resources to participate or did not understand how to do so. As a result, interviewees expressed frustrations with the GFSI not addressing their concerns. Further, fundamental differences in perceptions of how to create accountability undermined efforts to harmonize regimes. As with the LGMA, it is clear that the GFSI schemes will continue to overlay any U.S. government regulatory practices and could even potentially provide additional enforcement capabilities to the FDA. However, the differences in accountability, transparency, and participation again raise tensions regarding whether, and if so, how, the FDA can or should integrate the FSMA with the GFSI regulatory scheme.

II. Analysis of the Coexistence of Networks

The paper now turns to a discussion of the results of having these overlapping networks that operate with different systems and levels of perceived legitimacy and accountability. The networks are compared in terms of democratic differences, incentives, and barriers.

Perceived Democratic Differences

Stakeholders across the board commended the FDA for having done an excellent job of being inclusive, transparent and responsive. This is not an inherent, universal feature when government regulates, nor does it mean inclusion and influence was equal. Nonetheless, stakeholders' sense of legitimacy and accountability may be as important as their actual influence to the extent it translates into efforts to comply. Meanwhile, the industry-driven regulatory networks also have buy-in and trust from the stakeholders who are included. There is likely going to be continued demand for such industry-driven regulatory schemes because they can quickly respond to dynamic, changing systems and develop tailored regulatory systems that meet participants' specific needs. These networks are also undertaking efforts to be transparent, inclusive and accountable to broader stakeholders, although results are mixed regarding whether those efforts are successful or recognized.

Incentives for Harmonizing and Coordinating

Numerous interviewees noted that FDA's resources are insufficient to achieve the training and inspections that will be needed. Examination of the LGMA and GFSI networks raises a number of sensible reasons for the FDA to develop regulations and systems of enforcement that can integrate with industry-driven regulatory networks.

One of the major issues in the FSMA is the potential regulatory burden for small companies. Likewise, small companies often struggle to achieve certification under GFSI schemes because of the technical expertise needed and high costs of audits. The GFSI approach was to bring producers

into compliance through the global market technical committee, an approach they also framed as a way for private regulation to help small producers achieve compliance with public laws. Any modifications written into other regulatory schemes to accommodate these sorts of concerns may undermine the GFSI's efforts, while any exemptions could effectively be nullified by the additional requirements imposed by the GFSI.

There are a number of concerns raised about training of inspectors and achieving consistent enforcement, particularly as the FDA devolves responsibilities down to the states. These issues are being tackled in GFSI's technical working committee on auditor competence. This work could productively inform the FDA's training efforts, while the actual enforcement activities can augment the FDA and states' inspection programs. However, the utility could be limited to the extent private auditors and government inspectors have different discretionary authorities and must apply inconsistent standards.

Finally, for the FDA, developing tailored, flexible regulations for specific sectors is a clear challenge when writing comprehensive regulations. Where the FDA's standards fail to address known issues in specific commodity or nuanced market demands for exports and niche markets, standards such as those used in the LGMA could augment the FDA's standards. For these schemes to enhance the FDA's efforts, the FDA's regulations must foster regulatory co-existence.

With regulatory activities of these networks increasingly overlapping, resolution of conflicts and redundancies is important for preventing inefficient enforcement and partial compliance as producers struggle to meet costly and inconsistent demands of multiple regimes. This creates incentives for the FDA to write regulations that integrate smoothly with standards regimes such as the LGMA and the GFSI.

Barriers to Harmonization: Same Issues, Different Actors and Procedures – How to Reconcile?

A number of potential barriers to harmonization exist. Interviewees noted that writing and enforcement of the rules needed to be based on a uniform expertise and techno-scientific knowledge, so the regulations should be relatively consistent. Yet the issues of risk and science are framed by stakeholders' perspectives, so the idea that consistency should happen simply because it is the same science is problematic. The participation of different stakeholders potentially creates non-compatible regulations because the regulations may address different concerns. The FDA may rely on substantially the same science but make different interpretations of the science and different decisions about how to balance risks against other tradeoffs such as economic consequences.

A related issue is that the science is unclear and rapidly changing; thus decisions based in science may need to be made and revised under conditions of significant uncertainty and change. Again, the FDA may make different choices than other entities because of the differences in stakeholder participation. Furthermore, the systems of participation and accountability slow down the FDA by forcing it to go through time consuming and resource intensive engagement processes and procedures for justifying final rules to disparate overseers. This plodding process is problematic given the dynamic food system created by rapidly changing science and knowledge of food safety, as well as innovations in production and manufacturing and supply chain structures.

As an illustration of these issues, a major point of contention was how to evaluate the adequacy of water for irrigating and washing crops. The FDA proposed using the EPA's recreational water standard, which the LGMA also currently uses. However, this only measures generic E. coli, which can be an unreliable indicator of virulent pathogen presence. As a result, there was significant opposition to this proposal. While the LGMA standard is perceived as easily revised, critics feared that the ossification of rulemaking would lock the FDA into an inappropriate standard as new

science emerges. The FDA also received comments taking vastly different approaches to trading off risks and costs. These ranged from proposing more accurate, protective standards, such as requiring testing for specific pathogenic organisms, to less costly, easier to comply with standards, such as only requiring testing within a time window relevant to harvest.

III. Implications

Quandary for FDA – Incentives for Harmonization, Barriers

These observations point toward a quandary. On the one hand, there are incentives for having consistency between the FDA standards and others in order to reduce regulatory burdens. Being based on the same expertise and knowledge, interviewees argued that all standards should largely be consistent. On the other hand, the GFSI and LGMA were perceived as responsive to only a narrow set of interests. So while it would be valuable for FDA to align these entities, the FDA must respond to a number of other issues and may ultimately generate rules that increase regulatory burdens rather than help to ease them through harmonization.

On the other hand, there is a larger problem in how the proliferation of these overlapping regulatory networks creates a higher order system that aggravates legitimacy and accountability problems. The proliferation of the institutions of governance confound the ability of stakeholders to participate, regardless of how ostensibly open and transparent and accountable they are, because many actors do not have the resources or capacity to monitor and participate in the multiple networks even if given the opportunity to do so.

For a number of stakeholders, being able to even show up and participate is a challenge. Resource constraints mean that stakeholders need to be strategic about where and how they participate. Thus, the proliferation of networks is a double-edged sword. While it allows for experimentation and the possibility of creating unique, tailored regulatory systems, it means decisions affecting stakeholders may be made in any number of places. Not only do organizations need to strategize

where they participate, they need to invest resources in monitoring the multiple networks where policy could be made.

Aside from having the resources to participate, groups also need to understand how to participate. The rules for participating in government systems are well-established and groups know what effective strategies they can use to influence outcomes. This can be seen in the FSMA where groups knew how to participate, had strategies that they expected to work, and understood why perhaps they did not work. In the newer venues, this was not the case. Organizations do not necessarily know how to participate in other regimes or even if they can.

What Good is Legitimacy and Accountability that Just Aggravates Imbalances?

In writing the rules for the FSMA, stakeholders indicate the FDA has done great on participation, but scholarship documents that power imbalances can pervade traditional regulation (Wagner et al., 2011). In analysis and comparison of the networks, it appears the differential in capacity to participate and influence governance is being further exacerbated by the proliferation of the networks that are characterized by different rules of participation and demanding resources to monitor and influence policy making. In the case of food safety governance, it is not clear that attempting to create transparency, participation and accountability in individual institutions has value if marginalized stakeholders only become less able to avail themselves of these hallmarks of democracy. This calls into question in whose benefit experimentalist, 'New Governance' processes will truly operate if more is not done to ensure equitable access to the overlapping governing networks.

IV. Conclusion

New Governance proposes a new way of governing, where government identifies innovative regulatory practices being experimented with locally and/or privately, and then standardizes and scales-up those practices to create flexible and dynamic regulatory systems. The concept has

emerged in practice and in literature that recognizes that governing occurs in complex, dynamic systems composed of networks of actors with unclear and changing relationships.

We need to examine how private regulatory networks intersect with public agency efforts to implement New Governance. This will provide better understanding of the legitimacy and accountability challenges emerging in contemporary governance patterns. In the case of food safety, two relevant regulatory networks, the LGMA and the GFSI, overlap with the FDA's implementation of the FSMA. These networks can respond rapidly to participants' needs with tailored solutions and command significant resources and expertise. Given their utility, many assume they are going to continue to exist and proliferate. Thus, it is sensible to explore how agencies can and should identify and adopt experimental practices developed in private and public-private networks.

However, these networks also raise difficulties in the realities of implementing New Governance. There is a tension between the FDA's efforts to develop comprehensive regulations that accommodate numerous conflicting interests and the proliferating networks that develop tailored regulatory regimes that respond to narrow interests. As they increasingly overlap, inconsistencies potentially create redundant or conflicting regulatory regimes. However, efforts at harmonization are hampered by legitimacy and accountability procedures that affect who influences regulations and the speed at which regulators can react to new conditions.

Certain stakeholders lack resources and knowledge to effectively participate in all venues, even if given a chance. For them, transparency, openness and accountability are of little value. Scholarship shows these disparities are ineffectually addressed by administrative law as it operates today (Wagner et al., 2011). This leads one to question whether new governance might only aggravate these disparities by expecting agencies to coordinate and integrate with other regulatory networks. However, a more robust study would be needed to test this claim.

The ideal of New Governance envisions agencies that can be nimble and flexible to dynamic conditions while remaining responsive to numerous stakeholders. While this may be possible, this paper builds an argument that administrative procedure law hampers agencies' ability to respond appropriately to dynamic conditions. At the same time, expecting agencies to respond dynamically to multiplicative regulatory networks threatens to aggravate pre-existing power imbalances. The crippling ossification combined with potentially weakened systems of participation and accountability raise a concern that the legitimacy and accountability of the emerging global food safety system, composed of local and national food safety systems, transnational private systems, and supra-national systems such as the World Trade Organization and Codex Alimentarius,.

This is not a wholesale condemnation of governance networks and efforts to develop alternative approaches to regulation. Institutions of regulation and governance reflect historical moments of efforts to balance competing normative values, including accountability, participation, transparency, efficiency, effectiveness and collaboration (Bingham, 2010; Mashaw, 2005). Scholars have shown that private regulatory networks integrated with government and civil society networks can improve transnational regulation (Gulbrandsen, 2014; Overdevest & Zeitlin, 2014; Toffel et al., 2015). Further, the norms for acceptability of approaches can be revised through continual interactions of the enactors and subjects of governance (Bernstein & Cashore, 2007; Bernstein, 2011). In addition, the coexistence of multiple regulatory regimes may foster competition among regimes to be perceived as more legitimate and accountable. This could spur development of institutional structures that can do a better job of simultaneously achieving legitimacy, accountability, efficiency and effectiveness.

Nonetheless, when judged against conventional democratic norms of legitimacy and accountability, the current patterns of U.S. food safety governance fall far short of the ideal. As the regulatory agency responsible for coordinating these networks, the FDA lacks the resources and necessary procedural authorization to handle the role it has been assigned. Yet it has thus far managed to

'muddle through' with implementing pragmatic approaches to handling its complex regulatory role (Lindblom, 1959), such that interviewees across sectors expressed, on the whole, satisfaction with the FDA's rule-writing process.

This raises two questions. First, do current governance patterns fall so far short of the ideal that they have become unacceptable, or does regulatory harmonization and collaboration with overlapping networks constitute a best-available, pragmatic approach to contemporary complexity? If this falls too far short, what is the path forward? Further evaluation of the interactions between governance networks, in the U.S. and other countries where this pattern is emerging, will be necessary to more fully answer these questions.

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Chapter 4: Entrenching and Contesting Neoliberalism through the Food Safety Modernization Act

Abstract

The strategic actions of civil society during the enactment and implementation of the Food Safety Modernization Act (FSMA) have restructured power relations in food safety governance in the United States. The process has reinforced corporate power, globalized food systems and neoliberal ideologies, but also has restructured power relations to give greater recognition and power to alternative agrifood systems advocates. The paper first introduces the power relations between industry, state, and civil society that were documented by scholars preceding the enactment of the FSMA. Then, using interviews with key actors and secondary documents such as news stories and legislative testimony, it analyzes how actors' strategies concerning the enactment and rulemaking of the FSMA and concurrent private sector practices have created particular outcomes and to what extent civil society organizations have been able to resist or enroll others in pursuit of their interests. The paper concludes with commentary on the implications the findings have regarding efforts to transform agrifood systems.

Introduction

On January 4th, 2011, President Barack Obama signed into law the Food Safety Modernization Act (FSMA), the United States' first major update to Federal food safety laws in more than 70 years. The political contests over the law's enactment and rulemaking offer circumstances for understanding evolving patterns of food safety governance in the United States within the context of globalization. On the one hand, the law is a step for the United States down the path of integrated public-private regulation, which has been seen in a number of other countries and sectors (Garcia Martinez et al. 2007; Lockie et al. 2013; Marsden et al. 2010; Verbruggen and Havinga 2014). This arguably increases the already well-recognized power of industry – and in particular transnational

corporations (TNCs) – to govern in lieu of and in partnership with the state (Clapp and Fuchs 2009; Fuchs and Kalfagianni 2010). On the other hand, a seemingly odd alliance of consumer groups, industry and the US Food and Drug Administration (FDA) aligned in favor of the bill, while opposition came from advocates of sustainable agriculture and alternative agrifood systems[110] (referred to as AAFS for the remainder of the paper). This exposed significant fracturing and restructuring of relations within civil society over legitimating and contesting the governing powers of the state and industry.

This paper explores how the conflicts among these groups during the enactment and rulemaking restructured power relations between state, industry, and civil society actors in the governance of food. After briefly reviewing the literature on the structure of state, industry and civil society powers, the paper will discuss how actors contested and restructured these power relations during the enactment of the bill and subsequent rule writing. The paper then discusses how concurrent efforts to assist businesses in achieving compliance with the new rules are legitimating and reinforcing neoliberal, corporate governance strategies. The analysis shows that each group of actors exercised its power to resist or enroll the power of others and argues that this has simultaneously contested and reinforced features of the dominant agrifood system. The final section concludes with commentary on whether power contests concerning the FSMA have meaningfully restructured power relations in the agrifood system.

A. Background and Research Question

Historically, the provision of public goods such as food safety was considered to be primarily and appropriately the province of government. In recent decades, the regulatory roles of state, industry and civil society actors have been restructured as actors have developed alternative regulatory regimes in light of nations' limited capacities to regulate global supply chains (Busch and Bain

[110] In this paper, alternative agrifood systems is used synonymously with alternative agrifood networks.

2004; Henson and Reardon 2005). A number of features of the current regulatory regimes have been documented by scholars.

First, though not new, has been the power of corporate and business interests to influence government regulation at multiple levels. Food regime theorists argue that the state over the past few centuries has operated to stabilize food and agriculture markets for the accumulation of monetary wealth, often at the expense of other societal interests (Burch and Lawrence 2009; Friedmann and McMichael 1989; Holt Giménez and Shattuck 2011; McMichael 2009b). At a global scale, Bonanno's research points to restructuring of state-industry relations in which the state's power has dramatically declined relative to that of transnational corporations (TNCs) (Bonanno and Constance 2008; Bonanno 1994, 2004). Research on the United Kingdom's food regulation likewise suggests that it has shifted toward an integrated public-private regulatory system that is dominated by TNC interests (Marsden et al. 2010; Marsden, Flynn, and Ward 1994). At a more local level, Stuart showed that, after an E. coli outbreak linked to California leafy greens, the major producers and handlers of leafy greens used a state regulatory mechanism to rebuild trust in their industry, but at the expense of small farmers and conservation practices (Stuart 2010). This corporate power is criticized to the extent that business agendas override other priorities, and the power is used to sideline or subjugate other concerns (Clapp and Fuchs 2009; Magdoff, Foster, and Buttel 2000; McMichael 2009a, 2012)

In tandem with corporate influences on states, scholars have noted the increasingly private governance of agrifood chains through standards and third-party audits, which are known as tripartite standards regimes (TSRs) (Loconto and Busch 2010). In the absence of strong state regulation, powerful actors – particularly TNC retailers – use standards, which are verified through audits and certifications by third parties and enforced through contract terminations, to manage food quality (Busch 2011; Fulponi 2006; Hatanaka, Bain, and Busch 2005; Henson 2008).

These trajectories of ascending corporate power and declining government and civil society effectiveness are not universal and uncontested. Actors may reshape governance networks to better serve their own interests, rather than acting as passive subjects of the exercise of power (Cheshire and Lawrence 2005). For instance, Higgins et al. show that farmers are not naïve subjects of standards, but may strategically use and manipulate them to their own ends (Higgins, Dibden, and Cocklin 2008). However, the rising power of retailers and emerging use of standards and tripartite standards regimes has opened spaces for actors to directly target retailers and the private sector to push for reform (Hatanaka et al. 2005). Campbell and Le Heron document a number of instances where public interest groups, religious organizations, and new social movement and consumer organizations engaged in dynamic and contested negotiations with traditional power-holders, such as retailers, over who has power to define 'quality' in food (Campbell and Heron 2007).

Though other actors use standards and certification to advance their interests, there is concern about the extensive capacity of TNCs to control and co-opt standards processes in ways that exclude other stakeholders and that shift costs and risks to weaker and marginalized actors (Busch and Bain 2004; Hatanaka, Bain et al. 2005; Konefal, Mascarenhas et al. 2005). For instance, Bain's study of the Global GAP labor standards as practiced in Chile demonstrated that the standards operate to advance the retailer's economic interests while providing little protection to workers (Bain 2010).

These dynamics are often linked with the implementation of neoliberal ideologies. The hallmark concept of neoliberalism is that state power must be largely restricted and used to promote governance through markets (Busch 2010a; Peck 2001). A key piece of the neoliberal implementation project has been the creation of international governance frameworks such as the World Trade Organization (WTO) which operate to restrict state power and promote global markets (Busch 2010a). In particular, the agreements on Sanitary and Phytosanitary Measures and

on Technical Barriers to Trade set limits on nations' authorities to regulate goods entering their country and encouraged harmonization to standards promulgated by international standard setting bodies such as the Codex Alimentarius. This opened up global markets and made existing private standards *de facto* mandatory, which facilitated the rising economic power of retailers and their capacity to organize globalized supply chains (Busch and Bain 2004). The adoption of food safety standards was driven by the multinational retailers' needs to manage risks and costs while addressing consumers' concerns and building trust (Fulponi 2006; Hatanaka et al. 2005). Yet other actors, such as members of civil society, also use standards to target the perceived destructive externalities of the dominant corporate food system (Bain, Ransom, and Higgins 2013; Hatanaka et al. 2005). These private standards and accompanying TSRs are considered a key practice for implementing the neoliberal economy (Busch 2010b; Loconto and Busch 2010).

The role of civil society in contesting and legitimating the neoliberal project has been the focus of much scholarly attention. Although numerous movements contest corporate control of food systems, a number of scholars have noted that many of these movements subscribe to the same neoliberal logics that support current corporate power (Holt Giménez and Shattuck 2011; Mares and Alkon 2011). Particularly critiqued have been the increasing use of standards and the focus on consumer action because they privilege the market and private action as effective strategies for change (Brown and Getz 2008; Guthman 2008).

Thus the enactment and implementation of the FSMA is occurring in a time when scholarly attention is focused on the roles of corporations, the state, and civil society in governing society. The scholarly narrative is that the power of corporations to govern in partnership with or in lieu of the state is often ascendant but contested. Meanwhile, ideologies of neoliberalism undergird this power and also pervade efforts to challenge the power structure. This paper explores these dynamics by asking: To what extent and in what ways did actors restructure power relations in

food safety governance in the United States during the debate and passage of the FSMA and the ensuing rulemaking?

B. Design and Methods

The FSMA was a highly contested, major revision to the U.S. federal food safety regulatory system. A case study examining the political contests over enactment and rulemaking of the FSMA enables exploration of the restructuring of power relations in food safety governance in the U.S. The research design explores actors' characterization of the structure and processes of regulation during enactment and rulemaking of the FSMA.

The primary data for the research came from 37 semi-structured interviews with staff in industry and civil society organizations, federal and state regulators, congressional staff, food safety and regulatory compliance lawyers, and academics conducted between November 2013 and September 2014. Initial interviewees were identified based on preliminary research of who the major participants were in the enactment and implementation of the law. Further interviewees were identified and contacted through attending industry and consumer food policy conferences, which were also used as observational opportunities for better understanding the issues and discourses of stakeholder groups. Additional interviewees were identified using a snowball sampling method by asking interviewees about their important partners and asking about stakeholders with whom they disagreed. This last question was asked to try to identify opposing views and ensure consideration of the full range of opinions. Interviewees were predominantly actors closely involved in policy making; thus some perspectives may not be fully included.

Interviews were recorded, transcribed and coded. Coding variables were developed deductively based on Marsh and Smith's conceptual framework of policy networks and policy change which was modified to examine policy making in multiple, overlapping networks (Marsh and Smith 2000; Toke and Marsh 2003). Additional codes were added inductively as new concepts emerged in the analysis.

Major coding categories included the venues of the policy networks, the structures of the networks, actor categories, actors' traits, actors' actions, characterizations of the process, and outcomes and impacts. The venue codes were the enactment of the FSMA and the FDA's implementation. Structural codes included codes about the rules of participation such as who may participate, what issues are considered for discussion, and how actors should participate. Actor categories included consumer organization, alternative agrifood organizations, the produce industry, food manufacturing industry, the FDA and state/local regulators. Codes about actors' traits included their strategic interests, resources, authority, and knowledge. Codes about actors' actions covered activities such as lobbying/advocacy, blocking/inaction, assuring or building trust, and learning/recognizing. Codes about actors' characterizations of the processes included transparency, participatory-ness, difficult/easy, and speed. Finally, outcomes and impacts included policy choices, accountability, trust, conflicting or confusing policies, doable-ness, and food safety.

Interviews were categorized into actor groups. Attribution of data points to individual interviewees was maintained throughout the analysis in order to keep track of the actor category of the interviewee. Codes about actors' traits and actions were sorted into groups according to the category of actor being discussed, then analyzed and summarized. Codes about outcomes, process, structure, context and actors traits' were analyzed and summarized were grouped according to whether events being discussed were during the enactment or the rulemaking.

Secondary materials, such as legislative testimony, comments during the rulemaking process, and media reports were also reviewed (but not coded and analyzed). This added additional understanding to the analysis of interviews.

I. Enactment of the FSMA

The FSMA was enacted after a tumultuous journey through Congress. Support for a food safety bill emerged following a series of high-profile food-borne illness outbreaks in common foods such as

peanut butter and spinach, as well as an incident involving intentional contamination of protein from China with melamine. A version of the bill passed the House in early 2009, when the House, Senate and White House were all controlled by the Democratic Party. The Senate did not pass their version until almost the end of 2010, on the eve of Republicans taking over the House. Despite broad support for the bill, opposition from AAFS proponents and anti-regulation libertarians threatened the viability of the bill at the end. This section will discuss the major actors' interests and strategies during debate and passage of the bill, as well as the final outcomes that were achieved.

The enactment of the FSMA was driven by an alliance between consumer groups, industry groups, and the FDA who all agreed there was a need to update FDA's regulatory authorities. The general consensus among interviewees was that the consumer groups played a pivotal role in raising and maintaining food safety on the political agenda, but the bill would not have passed without industry support. Consumer groups had long been advocating reform of the US food safety legislation. The Pew Charitable Trusts, recognizing that food safety was an issue on which they could have a meaningful impact, invested resources into research and advocacy. Thus the consumer organizations, with major funding from the Pew Charitable Trusts, formed the Make Our Food Safe Coalition to campaign for food safety reform and were able to fly in victims and victims' advocates to lobby in partnership with more experienced advocates. This gave them the ability to put a face on the numbers and bring well-developed arguments and strategies to Congress.

Industry as used here includes, but is not limited to, food manufacturers primarily represented by the Grocery Manufacturers Association, fresh produce growers represented by trade associations such as United Fresh Produce, the Western Growers Association and the Produce Marketing Association, and retailers represented by the Food Marketing Institute. Also present, but with a lower profile, were the private auditors who already played a major role in governing the private food safety system. For the food manufacturers and produce growers, the bill was a way to force

everyone to comply with a minimum standard and start using the same practices they were already being required to use by the retailers. For the retailers and auditors, the bill was a way for government to take on some of the enforcement and oversight that was seen as needed to help improve the private regimes. Thus there was widespread support for legislation throughout the major industry trade associations.

The bill was constructed from a combination of policy proposals put forward by the Center for Science in the Public Interest (CSPI), the Grocery Manufacturers Association (GMA) and the FDA. Given how long they had been advocating for reform, consumer groups had a well-developed policy agenda for food safety reform, which was crystallized in CSPI's white paper "Building a Modern Food Safety System." The white paper called for mandatory process controls for manufacturing; specific enforceable standards for produce; and stronger FDA oversight and enforcement through increased inspections, recall and detention authority, traceback provisions, the ability to sanction through criminal and civil penalties, and whistle blower protections. The proposal put forward by the GMA called for a far lighter touch from government. The proposal consisted of "four pillars", which would have required importers to ensure safety of imported foods, authorized FDA to develop a process for expediting entry of imports subject to stricter private food safety oversight, obligated FDA to build capacity of foreign governments, and expanded FDA oversight and enforcement capacities through additional personnel, equipment, laboratory capacity and scientific expertise. The plan would not have expanded the FDA's authority to enforce regulations. FDA's proposal fell somewhere between CSPI's and GMA's. The FDA's 2007 Food Protection Plan called for increased prevention to be carried out by industry and increased risk-based oversight and enforcement by the FDA. The plan proposed a number of additional authorities for the FDA, including allowing the FDA to mandate preventive controls, accredit third party inspectors for imports, charge a number of fees, gain increased access to records, and mandate recalls.

Opposition to the bill came from two groups. First, and unforeseen by the consumer advocacy coalition, AAFS advocates raised vehement objections to the bill. This opposition was coordinated by the National Sustainable Agriculture Coalition (NSAC). These opponents' concerns were twofold: the potential regulatory burden on the burgeoning local and alternative food systems practitioners, and potential conflicts with sustainable farming practices. Both concerns stemmed from expectations that regulations would be written to address problems of the intensified, concentrated, industrial food and agriculture system, resulting in inappropriate and unworkable regulations for small and diversified growers and manufacturers.

When AAFS advocates became aware of the likely enactment of the bill, the House and Senate had already held numerous hearings on food safety and negotiations on compromise text were already well under way. Thus, NSAC was somewhat late to the table and struggled to gain traction in the House. However, they did develop a message that food safety is everyone's responsibility but needs to be scale and risk appropriate, which gained them a few supporters in the House and a number of key champions in the Senate.

The second group that opposed the bill can best be characterized as libertarians opposed to any sort of regulation. They played an important role in the enactment process because their total opposition created credible threats to enactment of the bill. This bolstered NSAC's negotiating capacity in seeking modifications and exemptions tailored to alternative agrifood businesses.

In the House, AAFS and libertarian advocates struggled to find representatives who would oppose the bill. However, enough representatives were willing to vote in opposition to the bill that it failed to pass when Rep. Pelosi attempted to pass the bill under suspension of the rules, which requires a super-majority vote. Proponents of the bill were not expecting it to fail under suspension of the rules. The loss created ire among proponents and provided dramatic evidence that there was meaningful opposition to the bill. Though the bill passed the House under normal procedural rules, this was a symbolically important moment for NSAC. As the bill moved through the Senate, NSAC

had a number of Senators on key committees who were willing to introduce amendments favoring NSAC's goals. With their previous success in the House, and libertarians threatening the bill completely, NSAC was able to achieve a number of exemptions and provisions that otherwise might not have been possible.

Ultimately, as with most legislation, the bill included a series of compromises that accommodated different interests to differing degrees. The bill included requirements that FDA develop standards for food manufacturers and growers to identify and control potential hazards in their facilities and fields. The FDA's authority was expanded to include increased records access, mandates for more frequent, risk-based facilities inspections, and the ability to withdraw facilities' registration and mandate recalls. The bill also authorized the FDA to improve oversight of imports by requiring importers to verify the food safety practices of their suppliers, establishing expedited entry for manufacturers participating in voluntary qualified importer programs, and requiring certifications of food as a condition of entry. Thus, the bill put significant responsibility on industry to ensure the safety of the US food supply, while the FDA was to establish a minimum floor of food safety and hold industry accountable for failures.

A number of compromises were included to accommodate AAFS advocates. The most controversial was the Tester-Hagan amendment, which provided qualified exemptions for small and direct-sales businesses from having to comply with provisions in the processing and growing standards. Consumer groups and industry saw these as an exemption from food safety that put the entire system at risk, while proponents argued it was not an exemption so much as recognition that small-scale and direct sales present different risks that can be better managed through other mechanisms. Other provisions included a requirement that FDA study the small-scale and direct sales sector to better understand potential impacts, modifications to make record keeping and traceability less burdensome, and provisions prohibiting FDA from writing regulations that conflict with USDA organic standards and other federal conservation programs. These were all aimed at creating a

more flexible risk-based regulatory system that does not overly burden small and alternative food systems.

Thus, despite industry's pursuit of comprehensive, universal legislation, AAFS advocates were able to carve out a space in federal legislation that protects their vision of the food system from regulations designed for the industrial, globalized food system. While not yet at the point that they could pursue comprehensive legislation designed to foster and promote their vision of a food system, these successes were consistent with victories they have won in the Farm Bill over the years. Through advocacy efforts, the distinctive characteristics of AAFS are increasingly being recognized and addressed in legislation.

II. Rulemaking for the FSMA

With the successful enactment of the law, much of the work necessary to implement it shifted to the FDA. Implementation involves a number of activities, including writing legally-binding regulations that provide specifics on the broad provisions in the bill, developing guidance documents that provide direction in interpreting and applying the law and regulations, revising internal inspection and enforcement procedures, and establishing formal partnerships with state agencies to assist in implementation. The discussion herein focuses primarily on the rulemaking stage.

To write the rules for the FSMA, the FDA must follow legally mandated administrative notice and comment procedures which require the agency to issue a proposed rule, solicit comments from the public, make modifications as appropriate, and issue a final rule. Before issuing the initial proposed rule, the FDA solicited preliminary input for developing the rules. To provide documents to the public and gather public comments, the FDA created an official docket, available at regulations.gov, where all relevant materials were gathered. These are all procedures typical of a notice and comment rulemaking.

In addition to the docket, the FDA held hearings across the country for stakeholders to provide oral input that became part of the official record. There were also listening sessions and tours of farms and manufacturing facilities, which were not part of the official record but which informed the FDA's rulemaking. Lastly, FDA held regular meetings with various stakeholders to solicit feedback. None of these were required, but were permissible under ex-parte communication rules which require that any contact with stakeholders during the rulemaking must be documented.

Numerous organizations and individuals throughout the food supply chain were proactive about commenting and participating in hearings and listening sessions. Industry trade associations, consumer groups, academics, and state officials all submitted comments that contained factual accounts, legal analyses and scientific research that support their positions. Advocates from every sector were also represented throughout the listening sessions, telling personal stories and providing additional data to bolster their positions.

Comments from members and supporters of NSAC were voluminous. Building on their grass roots mobilizing experience, NSAC took the lead on organizing a letter writing campaign wherein they educated their members on the provisions in the proposed rules and emphasized the need to write distinct stories of how the proposed regulations would impact their businesses. NSAC also employed the Harvard Food Law and Policy Clinic to enhance their legal analysis. In contrast to the scientific and legal arguments occurring in many organizational comments, individuals' comments focused on educating the FDA on how their businesses or lives would be affected by the proposed rules. The FDA treated form letters as a single comment, so NSAC's campaign focused on getting numerous individuals to submit unique comments that address a common set of issues.

In addition to the notice and comment procedures and hearings and listening sessions, FDA held numerous informal meetings with stakeholders. Industry and consumer organization interviewees commented on these meetings being held almost monthly. State officials and AAFS described them as happening regularly but not necessarily monthly. The practice of holding monthly meetings goes

back to the George W. Bush administration, which initiated monthly meetings with the USDA for both industry and consumer groups. Consumer groups had been advocating for FDA to hold monthly meetings as well, but they were not initiated until Michael Taylor joined the FDA as Deputy Commissioner for Foods in 2010. Interviewees described the meetings as an opportunity for the FDA to explain their thinking and to receive feedback from stakeholders. FDA could not comment on potential policy changes as a result of the discussions and requested that participants submit any comments to the docket for formal consideration. Thus, the meetings were characterized as opportunities for dialogue, not lobbying and advocacy.

In response to the feedback the FDA received on the initial proposed rules, the agency issued a set of supplemental rules that made revisions to the initial proposed rules. Among NSAC's concerns that the agency addressed in the supplemental rules were:

- The definition of "farm", which failed to recognize the common practice of packing and holding produce from a number of growers
- Establishing procedures for withdrawing and regaining an exemption
- Changing some eligibility definitions to be based on sales of covered produce, not on sales of all foods
- Delaying implementation of regulations concerning manure until a risk assessment and further research on appropriate intervals are conducted.
- Modifications to the water testing and treatment requirements

Though NSAC characterized these changes in the supplemental proposed rule as a successful result of their advocacy, that claim should be qualified. The FDA's response in the supplemental rule indicated they were responding to extensive comments critiquing the provision's potential economic and ecological impact and the underlying science supporting the FDA's initial proposal. Thus, NSAC successfully influenced the FDA to delay implementation of the manure provision and to defer to the NOP standards despite opposition from the other stakeholders. However, on many of

the other provisions, such as refining the definition of farm and the water testing objections, NSAC actually had common ground with big industry over how problematic the proposed regulations would be. Their comments were further bolstered by comments from state departments of agriculture, which also indicated how problematic the provisions were. Thus, it should not be claimed that the FDA's changes on those provisions in the proposed rule were directly and solely the result of NSAC's letter writing campaign.

The value of NSAC's success is moderated by the fact that they used the same exercise of power that big industry has used to prevent implementation of laws and regulations that are meant to be protective of public health, which is to obstruct and delay until there's 'more science' when there may never be enough science (McGarity 2003). This can be seen as a coalition of businesses and their supporters, albeit small and self-identified as sustainable, replicating the industry exercise of power to capture agencies and avoid regulation.

Nonetheless, these victories should be recognized as indicative that AAFS advocates possess meaningful recognition and power to influence laws and regulations. The rulemaking stage can be as critical for establishing policy as enactment of legislation, and it is also far less high profile to the public. For the AAFS actors to have maintained advocacy momentum and impacted the rules is therefore noteworthy. Further evidence of the increased recognition of AAFS interests can be drawn from FDA stakeholders meetings. Consumer groups and industry are obviously still significant stakeholders for FDA to be communicating with, but AAFS advocates are not being ignored. Their regular meetings with the FDA indicate the FDA is taking them seriously as a distinct stakeholder group to engage. On its own, this data is fairly insignificant. Combined with the AAFS successes in the enactment of the law and with interviewees' across sectors noting AAFS has become a significant player, it suggests that AAFS advocates are gaining legitimacy and power as a distinct voice within civil society. Since their campaigns during rulemakings for the National Organic Program, AAFS advocates have been recognized in some quarters as a significant voice. The

enactment and rulemaking of the FSMA constitute another recognizable space where they are gaining legitimacy and power.

III. Concurrent Processes Further Entrenching Neoliberalism

Concurrent with the rulemaking for the FSMA, pre-existing market-based regulatory activities continued while new market-based efforts also emerged. For example, industry-based regimes such as the private, retailer-led Global Food Safety Initiative continues to gain momentum in adoption, and nothing rolled back the public-private, industry-led Leafy Greens Marketing Agreements in California and Arizona. Not only did these regimes continue to operate, industry advocated harmonization between FDA's rules and the industry-led regimes. Some interviewees expressed beliefs that, should FDA align its regulations with these industry-led initiatives, the retailers and industry could better act in a regulatory partnership with the FDA. So it should be recognized that there continues to be a dominant, industry-led regulatory regime that exists outside of the state and that its proponents are advocating operating as co-regulators with the state.

The general consensus in interviews was that, despite their exemption from the FSMA, small and midsize businesses – both alternative and conventional – would need significant assistance to achieve compliance with the 'modern' food safety standards envisioned in the FSMA. Interviewees also expressed a belief that, even with the exemptions, many producers and suppliers were still going to be required by their buyers to achieve food safety certifications to be able to participate in the evolving food marketplace. Thus, training and education for farmers and food manufacturers was considered critical for maintaining the economic viability of small and midsized businesses. Federal and state agencies undertook a number of initiatives to develop and deploy training and educational materials for these businesses. This included funding authorizations in FSMA for technical assistance, grants from the FDA to universities for developing training curricula for

farmers and manufacturers and the expert advisors that serve them, and a number of auditing efforts by the USDA, industry and non-profits to get smaller entities certified to Good Agricultural Practices (GAPs). These initiatives were not exclusively targeting alternative food chain businesses; they were aimed at anyone that had not to date achieved compliance with the floor of industry standards. However, some are explicitly trying to work with alternative chains. For instance, there was a USDA Group-GAP pilot project being undertaken with consortia of small farms to try to figure out how to make GAP more affordable in order to enable more institutional sales by small farmers. Further, civil society actors – both consumer groups and small farm advocates –participated in private initiatives to regulate food safety. For instance, consumer groups partnered with farmworker organizations and retailers to establish the Equitable Food Initiative (EFI). This is a privately developed standard for food safety, working conditions, and pesticide exposure that is adopted by retailers and food service providers and enforced through third party audits. On the AAFS side, the On Farm Food Safety Project, an initiative of FamilyFarmed.org, developed online training and tools to help small and midsized growers achieve food safety certification.

The continued operation and perceived power of the marketplace to impose standards above and beyond federal requirements suggest that little was done to check neoliberal market governance. Further, the initiatives to train and motivate growers and manufacturers to self-enforce are examples of increased efforts by both public and private actors in support of governing through markets.

IV. Perspectives on Change

Though the substantive outcomes in the legislation, rulemaking, and overall governance appear perhaps paltry under the analysis so far, the narrative should not be read as a condemnation of AAFS advocates' efforts. Throughout the interviews, it was clear that prior to the contests over the bill, AAFS had not been recognized as a distinct sector of civil society in domains other than

agriculture policy. The vocal opposition and on-going advocacy helped establish NSAC and related groups as distinct and legitimate participants in governing. This recognition of the groups can be seen as a step toward becoming a stronger political player.

Consumer groups accomplished a similar step thirty years ago and have by now coalesced into a significant political player. When asked what has changed over time for consumer groups, they discussed thirty years ago encountering a piece of legislation they opposed and having to rally late in the legislative process to defeat it. After defeating the bill, the groups made more concerted efforts to coordinate legislative monitoring and advocacy. Several interviewees commented that, over time, with consistent advocacy and demonstrating that they can make themselves a problem for industry, consumer groups are now generally treated as a necessary party to have at the table when developing consumer protection regulations.

In the FSMA, AAFS advocates successfully obtained a place at the table. If they continue engagement in future policy making, the advocacy successes in FSMA could someday be seen as a turning point for AAFS advocates in becoming a powerful and necessary stakeholder to include in agrifood systems governance processes.

V. Enrolling, Resisting, Restructuring

The contests over food safety governance in the United States demonstrate simultaneous processes of multiple actors' attempts to resist and enroll the power of others in pursuit of their interests. While the dominance of industry interests is evident, the power dynamics also reveal spaces where the state continues to play a preeminent role in governing society and opportunities where civil society effectively used the power dynamics to attempt to reshape the outcomes.

A. Industry Enrollment of State and Civil Society

As noted by Pierre and Peters, the role and capacity of the state is not inherently diminished – states retain power to reassert control, should they choose to exercise it (Pierre and Peters 2000:5).

Here, the government has authority to impose regulations on the full spectrum of actors in the food supply, while private entities can only control those actors in their supply chain. Thus, as industry faced continued outbreaks, it turned to government to solve a problem they could not – establishing and enforcing standards for production and manufacturing that would impose a universally applicable floor. The produce industry, food manufacturing industry, and audit industry all in varying ways wanted the FSMA to enroll the power of government in cleaning up the bad actors in their fields that they had been unable to police heretofore.

Activities were not just about enrolling the state to exercise enforcement authority that industry does not have. Activities also focused on enrolling the state in partnering with and legitimating the private regulatory activities of industry. The marketing agreements in Stuart's (2010) study created a forum for ongoing interactions between the leafy greens industry, state regulators, and now the federal government. This allowed the industry to educate the state on their practices and encourage adoption of their regulatory practices as the law of the land. Interviewees from the leafy greens industry and AAFS advocates both commented that the proposed rules reflected FDA's understanding of the produce industry in California, but showed a poor knowledge of differences in the rest of the country. The audit industry as well sought to use the enactment and rulemaking processes as an engagement opportunity to persuade the FDA to better understand and partner with the private auditors. Finally, state and civil society initiatives to educate and train growers and food manufacturers support implementation of regimes of standards and audits. Thus, the state and civil society are also contributing to governance through private markets.

B. State Relations with Industry and Civil Society

At the same time that industry sought to enroll the state's authority in legitimating their regulatory activities, the FDA needed to enroll the industry's regulatory capacity in achieving their regulatory goals. An industry interviewee and agency official both noted the outreach and engagement of the FSMA rulemaking process was important because the FDA lacked expertise regarding industry

practices that is needed to effectively implement a new regulatory regime. Industry and civil society interviewees noted that the FDA lacks the necessary resources to fully inspect the value chain and enforce the law – thus the agency needs the industry to act as a regulatory partner, assisting in oversight. This follows the trajectory of processes of privatization and devolution of government to lower levels, thus hollowing out the state and forcing partnering with and legitimation of the regulatory capacity of industry.

While the outreach and engagement process enrolled industry, it had an added benefit of also enrolling civil society actors to produce trust in the legitimacy of the FDA's activities. Continuous dialogues with civil society actors, numerous listening sessions, and revising the proposed rules and responding to comments all created a general sense that, even if they did not ultimately get their way, most groups felt that FDA had listened and heard them and sought to find a balance.

C. Civil Society: Fragmentation, Ascension and Resistance

While much of the story of the FSMA is one of a weakened state further enrolled to serve corporate interests, it is not the whole story. The full picture includes a civil society that is fragmented but still capable of leveraging power dynamics to achieve the ends of its members. Perhaps, over time, the various sectors of civil society will become more sophisticated and more effective at targeting both public and private regulatory actors in order to counter the power of TNCs that has been documented by scholars (Bonanno 2004; Clapp and Fuchs 2009).

The first facet of civil society to be addressed is the fragmentation and power restructuring that occurred within civil society during the enactment of the legislation. This is noteworthy because it suggests that AAFSs could be at the early stages of emerging as a separate stakeholder group, capable of traveling the trajectory that consumer groups have followed.

Consumer advocacy organizations are generally recognized as a legitimate civil society voice and are included in a variety of private, public-private and private rulemaking activities. Many consumer groups have belonged to a long standing coalition that emerged in the late 1980s, in part as a reaction to a piece of legislation that caught them off guard. By the time the opportunity for enactment of the FSMA came about, consumer advocacy groups had been organizing and agitating in a loosely coordinated form for three decades. Their policy proposals were well developed and networks for action ready to mobilize. As a result, consumer groups were characterized as playing a pivotal role in driving the FSMA forward and maintaining food safety on the public agenda.

In contrast, the AAFS organizations were somewhat caught off guard by the FSMA and its potential impacts on AAFS. Yet they were able to leverage industry's need for government intervention to achieve a number of perceived wins. They see themselves as having a strong history of mobilizing grassroots networks on the farm bill and the organic program, and the FSMA was characterized by them and other stakeholders as a moment where their distinctive issues and power to oppose and genuinely threaten industry interests came to the fore. This has carried through into their effective advocacy in the rulemaking for the FSMA. The recognition is further reinforced by state and federal training initiatives targeting the unique needs of smaller manufacturers and producers. These all indicate that AAFS advocates are today where consumer groups were when they coalesced in the early 90's and are becoming increasingly effective as a distinct advocacy network.

Despite these apparent successes of consumer groups and emerging recognition of AAFS advocates, there are some shortcomings to be discussed. First, in large part the exemptions in FSMA did little to nothing to check the global regulatory power of TNCs. Rather, the law as a whole entrenched and legitimated neoliberal governance mechanisms and replicated the public-private regulatory regimes that have already been documented throughout other parts of the world (Marsden et al. 2010; Verbruggen and Havinga 2014). If anything, consumer groups' alliance with industry to

support FSMA has operated to further entrench the capacity of the corporate food system to recover from crises and continue operating globally.

Second, the successes documented herein are potentially reflections of unique political windows more than evidence of increased recognition and power for AAFS advocates. When the FSMA was enacted in 2010, it was on the eve of the House switching to a Republican majority. Proponents were desperate to get the bill passed under a Democratic House and Senate. With the added opposition of libertarians, AAFS advocates were able to threaten the enactment of the bill. In some ways, as the potentially regulated industry, this can also be framed as a fragmentation within industry rather than civil society and a classic case of industry capture and delay. Likewise, AAFS advocates' success in the rulemaking process came at a time when the agency leadership was committed to trying to address all stakeholders' concerns in implementing the FSMA. Further, the agency is writing the regulations under conditions of a severely constrained and threatened budget so it must be sensitive to not alienating stakeholder groups who could leverage Congressional power to threaten the agency's funding. In different political climates, AAFS advocates may not have been able to successfully to threaten dominant sectors in order to extract concessions.

Third, there is a debatable point regarding to what extent civil society is successfully achieving their goals versus being coopted into a neoliberal governance regime. On the one hand, civil society is leveraging industry's power and vulnerabilities to achieve social agendas, and their advocacy efforts are not limited to exclusively focusing on state regulation. Examples include the Equitable Food Initiative and emerging efforts to help small and alternative agriculture programs achieve food safety certifications. On the other hand, by participating in private standard setting and enforcement initiatives, these actors have been enrolled or coopted into supporting globalized, corporate interests and neoliberal governance mechanisms.

VI. Conclusions

The enactment and implementation of the FSMA represents a potentially important juncture in food safety governance in the United States. On the one hand, the law sets the United States further down a path of blurred public-private regulation that is being seen in a number of other countries. Though some private regulation is carried out by civil society, the law relies heavily on industry-developed and driven mechanisms. Thus, it is arguably further entrenching patterns of corporate power and accompanying negative impacts on human and environmental well-being that have been maligned in agrifood scholarship (Clapp and Fuchs 2009; Magdoff et al. 2000; McMichael 2009a, 2012). On the other hand, AAFS advocates that were opposed to the bill's seemingly corporate agenda successfully achieved concessions in the bill to accommodate AAFS. Concurrently and following up on the bill, a number of private and state-led initiatives emerged to provide technical and educational support to small and alternative food systems. Thus, it was arguably a point of successful contestation of corporate regimes and exploitation of governance patterns to serve their own ends. This prompted the question: To what extent and in what ways did these political contests restructure power relations in US agrifood governance?

The analysis reveals divergent possible interpretations that can answer this question. Interviewees across sectors noted that the successful opposition by NSAC and its allies revealed a significant, previously unrecognized divide in civil society. For many, it was characterized as a meaningful turning point in AAFS being recognized as a distinct area of concern. From one perspective, this can be seen as a significant moment where AAFS advocates gained increased legitimacy and power which they can build on for future successes. It has parallels to the trajectory consumer groups have taken to achieve their recognized role as necessary stakeholders in agrifood governance, so it is plausible to hope that this is a step for AAFS advocates toward being a more powerful stakeholder group. NSAC's vocal opposition leveraged industry interests in the bill to force concessions, influenced FDA to revise proposed rules in their favor, and then has achieved having a number of state and private resources funneled toward their constituencies. Given the power disparities and

enormous resources that went into NSAC's successful campaigns, this should be recognized as a meaningful success.

However, the extent of success is moderated by a number of factors. First, the law for the most part does re-entrench corporate power and enroll the state in legitimating and supporting globalized, corporate food chains. Though it carves out a safe space for AAFS, it does little to repeal the roll-out of neoliberalism and accompanying rise of corporate power. Given this, many interviewees expected that the exemptions would be made moot to the extent that the corporate supply chains continue to dominate agrifood systems and producers would be required to comply with the demands of those supply chains, whether the law requires it or not. Second, the contests over the bill raised awareness of how unprepared many producers are to meet the requirements of the new law, let alone the higher standards of private supply chains regulations. While this has meant civil society and state resources are now going toward helping small farmers and manufacturers in achieving compliance, this can also be interpreted as state and civil society resources being enrolled and coopted into supporting the neoliberal corporate food regime. Finally, the political successes are somewhat a factor of the political climates during enactment and rulemaking. Despite the successes here, it should not be assumed that NSAC can be equally successful in the future under different political conditions.

The dual answer to the question of how power has been restructured points to future challenges facing AAFS advocates. Given the effort and resources and historically marginalized role of AAFS in federal policy, any success at carving out a safe space for AAFS should be recognized. However, scholarly critiques that contestation often reinforces neoliberal ideologies and fails to effectively reform policies that support the current corporate food regime (Brown and Getz 2008; Guthman 2004, 2008; Holt Giménez and Shattuck 2011; Mares and Alkon 2011) hold true in this case. It should not be surprising that the most effective advocacy initiatives exploit the dominant logics and narratives and use the same strategies that have been effective for industry. AAFS advocates face a

difficult task of restructuring the globalized regimes, corporate power, and neoliberal ideologies within a context where these concepts are pervasively normalized for much of society (Peck 2001). In this ideological context, the power contests in this study highlight the need to create compelling narratives and adopt effective advocacy strategies for transforming agrifood systems, but validate scholarly critiques of how hard this has been to achieve in practice.

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Chapter 5: Review and Conclusions

Overview

The contemporary, global, industrial food system is often described as broken and unsustainable. Transnational corporations, capital accumulation imperatives, and neoliberal ideologies are frequently (sometimes implicitly) singled out as the root causes of the ills and harms of the system. There are numerous ways to attempt to counter these destructive forces. Movements for food sovereignty, community food security, food safety, food justice, organics, fair trade, and local food systems all constitute efforts to reform the system to be better for the environment and the marginalized communities and social actors across the agrifood system. Sooner or later, all of these reform efforts will have to address the policies that steer the behavior of actors in the food system they seek to change.

Current governance scholarship highlights that policy reform does not just entail changing government policies. Rather, there is a proliferation of networks composed of public and private actors engaged in setting, applying, and enforcing rules in all manner of venues and scales. This is leading scholars to analyze how overlapping and interacting regulatory networks are changing the regulatory capacities and appropriate roles of different sectors and institutions in society. Some key questions include how are the overlaps among these networks shaping policy choices; how are these emerging institutional forms shaping actors' opportunities to participate in governance ; and how is the distribution of power across sectors being restructured? These questions all concern the impacts of these changes on different actors' ability to meaningfully influence the governing of their lives. For proponents of change, this intellectual pursuit may contribute to finding effective leverage points for tipping the system toward sustainability and justice.

The enactment and rulemaking of the Food Safety Modernization Act provided a constructive opportunity for exploring these questions because the enactment and rulemaking were and are significant points in the evolving relationships between public and private regulation. Identifying

who the social-political actors are that are involved in food safety governance in the U.S. -- and examining the power dynamics, interactions, relationships, institutional structures and outcomes of different regulatory regimes -- contributed to understanding the pragmatic challenges of developing appropriate tools for grappling with the dynamic complexity of contemporary agrifood systems. This endeavor has also shown how greater interdisciplinary cross fertilization can contribute to more thorough analysis of contemporary governance patterns.

Section I provides a synthesis of the findings of the three papers, and explains how the synthesized findings contribute to each domain of scholarship. Section II offers suggestions on future directions for research and commentary on the implications regarding governance of agrifood systems.

Contributions of the study

I. Review, Synthesis and Findings

A. Review of Literatures

The scholarship this study drew on can be loosely categorized into two broad areas of inquiry that cross a number of disciplines and sub-disciplines. The first is governance studies, which emerge from political science and have affinities with regulation studies and administrative law. The second is the agrifood governance literature, which draws on the governance studies scholarship, but primarily consists of sociology and geography studies of agrifood systems. Both broad areas are concerned with the emergence and implications of private actors taking on regulatory activities that had been considered the appropriate province of government for much of the 20th century. However, they emerge from different fields and focus on different questions and issues that are raised by the privatization of public action. The political science and regulation lines of governance focus on the roles and activities of state and non-state regulators and raise issues regarding how to design emerging governance institutions to promote both normative procedural values such as legitimacy and accountability. Agrifood governance studies reveal deep anxieties over how the distribution of power across sectors is affecting actors' current and future material wellbeing and

their capacities to exercise choice and influence over their lives. Thus, using both in an examination of food safety governance in the U.S. contributes different nuances for better understanding evolving governance patterns.

B. Synthesis of Findings

The first paper explains how the FSMA ended up as a set of policies that elevate and potentially legitimate private governance, and put the FDA in a difficult position of simultaneously partnering with but at the same time regulating the private sector – in a condition of severe resource constraints. Kingdon's model of policy streams posits that policy options are softened up and tested out in multiple networks before being enacted into law (Kingdon, 2003). The policy network framework provided a heuristic for incorporating Kingdon's model into explanations of contemporary governance processes consisting of multiple policy cycles within overlapping policy networks. The research showed that actors' participation in multiple networks can critically impact policy formation and choices. The process and outcomes documented in this paper highlights the importance of monitoring and participating in the proliferating policy networks.

The second paper demonstrated that this is problematic. The proliferation of policy networks and institutional forms limits resource constrained actors' capacities to meaningfully participate in all the relevant networks. This potentially undermines legitimacy and accountability in the overall system even as individual networks are increasingly initiating legitimacy and accountability procedures. Although other scholars suggest that overlapping networks can improve the effectiveness of standards and democracy procedures, this paper suggests the overall proliferation may simply aggravate pre-existing power imbalances. Further, different institutional forms potentially generate conflicting regulatory outcomes that can undermine overlapping regimes. This complicates the regulatory challenges facing public administrators, because they face tensions between incentives to harmonize with other regulatory networks and barriers resulting from disjointed systems of legitimacy and accountability.

This calls into question where to go with these alternative regulatory practices? At this point there is general consensus that overlapping networks will characterize regulation and governance for the foreseeable future and government institutions will retain authorities that will guarantee their continued exigency as regulatory actors. Yet it is unclear how or whether traditionally conceptualized government regulatory institutions can manage the complexity or play a role in transitioning into newer, stronger forms of interconnected regulatory networks.

The third paper takes up this issue of the distribution of power and whether anything can be done about these imbalances by exploring whether and to what extent the enactment and rulemaking of the FSMA have restructured power relations. The law takes the U.S. down the path of co-regulation that has been seen in countries such as the UK (Marsden, Lee, Flynn, & Thankappan, 2010) and the Netherlands (Verbruggen & Havinga, 2014). In many ways, this is further implementing neoliberalism by further entrenching the state in the role of supporting and legitimating market-based governance and facilitating global trade. These processes drive the structural power inequities that are maligned in the sociology literature and underlie the imbalances that were being aggravated in the analysis done in the second paper.

There was also recognition that little had been done to roll back corporate power. Consequently, governments and civil society are investing in training and support to help small and midsize producers develop and verify their food safety expertise and practices and thereby gain access to larger markets. This is a further roll-out of neoliberalism that supports and promotes food safety governance through market based mechanisms.

However, one can also interpret the outcomes as successful moments of contestation. Alternative agrifood systems advocates successfully leveraged industry's desire for government regulation to exact concessions to protect alternative agrifood systems. This was seen as a significant moment where the recognition and power of alternative agrifood advocates increased. Perhaps there is reason to believe that alternative agrifood systems advocates are building power and in the future

could be more effective at challenging corporatist food regimes. Yet this must be moderated by the recognition that the processes and outcomes used to contest the corporate power also replicate the corporate and neoliberal logics.

C. Contributions to the Scholarship

Political Science Framework

The conceptual framework for this study came from the political science policy networks literature. Scholars in political science have debated the terminology and value of policy networks for explaining and understanding policy change (Bevir & Richards, 2009; Borzel, 1998; Börzel, 1997; Dowding, 1995, 2001; Marsh & Smith, 2001). While conceptual clarification and testing is needed (discussed below in future research directions) the framework proved to be a very useful heuristic for grasping the complexity of interactions between actors, networks, outcomes and impacts. This research has merely peeked in on the conceptual utility of policy networks, but it suggests that the concept merits further exploration.

Regulation and Governance Studies

The regulation and governance studies highlight the need to focus on the emergence and practices of non-state regulatory actors. Much of the previous scholarship focused on describing and explaining the emergence and operation of private regulation. However, scholarship is starting to move towards examining the interactions between public and private regulation. Examination of the FSMA processes and overlapping policy networks offered an ideal opportunity to contribute to this line of scholarship. The modified policy network framework appears to be a useful heuristic for organizing the networks and actors and explaining how policy choices in one network translate into different policy choices in another network. Examining the impacts of the proliferation of networks on legitimacy and accountability in individual networks and the overall system also highlighted the importance of examining the overlapping networks. There is strong consensus that overlapping

public and private regulatory networks will be the norm for the foreseeable future. Understanding actors' capacity to meaningfully participate in governance, and what roles traditional regulatory states should play, are essential issues to be explored.

However, the other areas of scholarship suggest a potential critique of this line of inquiry. In some ways, accepting the proliferation of networks of governance is normalizing a very neoliberal conception of governing as something that should be done by a multiplicity of competing governors (Peck, 2001) – it is creating a marketplace of governance options. Administrative law scholarship recognizes the inequities and procedural inadequacies that plague conventional administrative law (Lobel, 2004; Mashaw, 2006; Wagner, Barnes, & Peters, 2011). Examination of the FSMA and overlapping networks suggests that such a neoliberal approach to governing perhaps only aggravates these inequities. As Busch suggests, as a society we should pause to examine whether the path we have laid out is taking us where we want to go (Busch, 2010b). Regulation and governance scholarship is not blind to this concern – scholars have argued that there needs to be a reconsideration of how concepts such as responsive regulation can be co-opted by advocates of neoliberalism to promote their political agenda (Grabosky, 2013) and a need for greater attention to how regulatory solutions become new sources of unequal and unjust power differences (Parker, 2013).

Administrative Law

The administrative law scholarship and praxis analyzes and conceptualizes what roles and procedures to assign to government regulators in the increasingly complex and dynamic environment of contemporary society. The findings of the research problematize several components of this project.

First, the research demonstrates the challenges of trying to create a regulatory regime that is legitimate and accountable. This is a pervasive, cyclical problem that is considered in administrative law scholarship (Mashaw, 2005; Stewart, 1975). Conventional impulses about how

best to ensure accountability are particularly counterproductive to creating regulatory regimes that can write, implement and enforce effective rules (Freeman, 1997). This suggests a need to clarify and re-conceptualize the normative values we use to evaluate governance regimes, especially as the boundaries between domains of governance become increasingly unclear (Bernstein & Cashore, 2007; Bernstein, 2011; Mashaw, 2005).

Second, however, is a danger that the normative value pervading the scholarship on alternative regulatory practices is that of neoliberalism. At times, the emphasis on achieving flexibility, innovation, and diversity starts to sound like concepts of market-like governance have become pervasively normalized in the scholarship (Peck, 2001). As with the regulation and governance studies, this danger is not un-recognized (Cohen, 2010). But again, it calls for a pause to ask whether this is truly the governance path we want to take (Busch, 2010b), even if it perhaps seems the only option available right now. States could reassert greater centralized control over economies (Pierre & Peters, 2000), and so it is important to keep in mind how the presence (or absence) of the shadow of state hierarchy can shape private regulatory networks (Borzel & Risse, 2010; Gulbrandsen, 2014; Héritier & Eckert, 2008).

This raises a third issue, which is the power dynamics in the iterative relationships between private regulatory networks and public regulation. Administrative law has concerned itself with how to design regulatory institutions to serve particular normative values, but what hope is there of achieving such regulatory design in a political system where the structure of regulatory institutions is potentially decided by the actors who will be subject to those regulations. Thomas shows industry support for public regulation only emerges when recurring crises in agrifood systems align industry's economic interests with publics' interests in industry regulation (Thomas, 2014). This research has shown that the same power dynamics that undermine equitable participation in administrative practice also problematize the potential for any institutional reform of said administrative practice.

Agrifood Governance

The findings of this study are not novel for agrifood governance scholarship – despite efforts to contest corporate food regimes, the U.S. continues down the same path of complex, integrated regulation dominated by corporate interests that is seen in countries such as the UK (Marsden et al., 2010). Further, many of the efforts at contestation fall prey to the same neoliberal logics and practices that underlay the structural problems (Brown & Getz, 2008; Guthman, 2004, 2008; Holt Giménez & Shattuck, 2011; Mares & Alkon, 2011).

One starts to wonder if this pattern is inevitable. If so, perhaps the scholarship is missing an opportunity to construct a more strategic way to exploit current governance structures. Rather than bemoaning ineffectual contestation efforts and railing against neoliberalism, could a more agnostic approach to the possibilities of institutional design in a neoliberal order, as is taken by the regulation and administrative law scholars, reveal opportunities for greater change?

The regulation and governance scholarship is showing that a strong civil society engaged with a strong state can strengthen transnational regulation (Gulbrandsen, 2014; Toffel, Short, & Ouellet, 2015). In this light, the growing power of alternative agrifood advocates evidenced in the contestation of the FSMA appears more significant. Over time, even if coopted into the regulatory regime, they could develop the capacity to have much more meaningful impacts.

II. The Future of Governance Scholarship & Praxis

The research started with the premise that efforts to create change in the agrifood systems must examine what laws and policies are currently in place, what are their consequences, what needs to be changed, and how can that change be achieved? This inquiry is premised on three notions: (1) the rules necessarily create winners and losers; (2) the rules must be changed in order to change the problematic outcomes being documented in the contemporary agrifood system; (3) the process of setting, application and enforcement of the rules must be understood in order to change them.

Although historically this may have required examining just the actions of government and the networks of actors engaged in lobbying and implementation, contemporary governance is characterized by considerably more complexity. Multiple, overlapping networks of public and private actors are continually renegotiating and restructuring the regulatory roles and regulatory capacities of different sectors of society. Particularly noteworthy has been the rise of private standards regimes that increasingly interact with state regulatory networks, at various times coexisting, competing, enhancing, or transforming states' regulatory apparatuses.

This pattern of governance raised three questions that concern the impacts of these changes on different actors' ability to meaningfully influence the governing of their lives.

1) How are the overlaps among these networks shaping policy choices?
2) How are these emerging institutional forms shaping actors' opportunities to participate in governance?
3) How is the distribution of power across sectors being restructured?

The exploration of these issues through examination of the enactment and rulemaking of Food Safety Modernization Act in the shadow of overlapping public-private and private regulatory networks points toward future directions for both research and praxis.

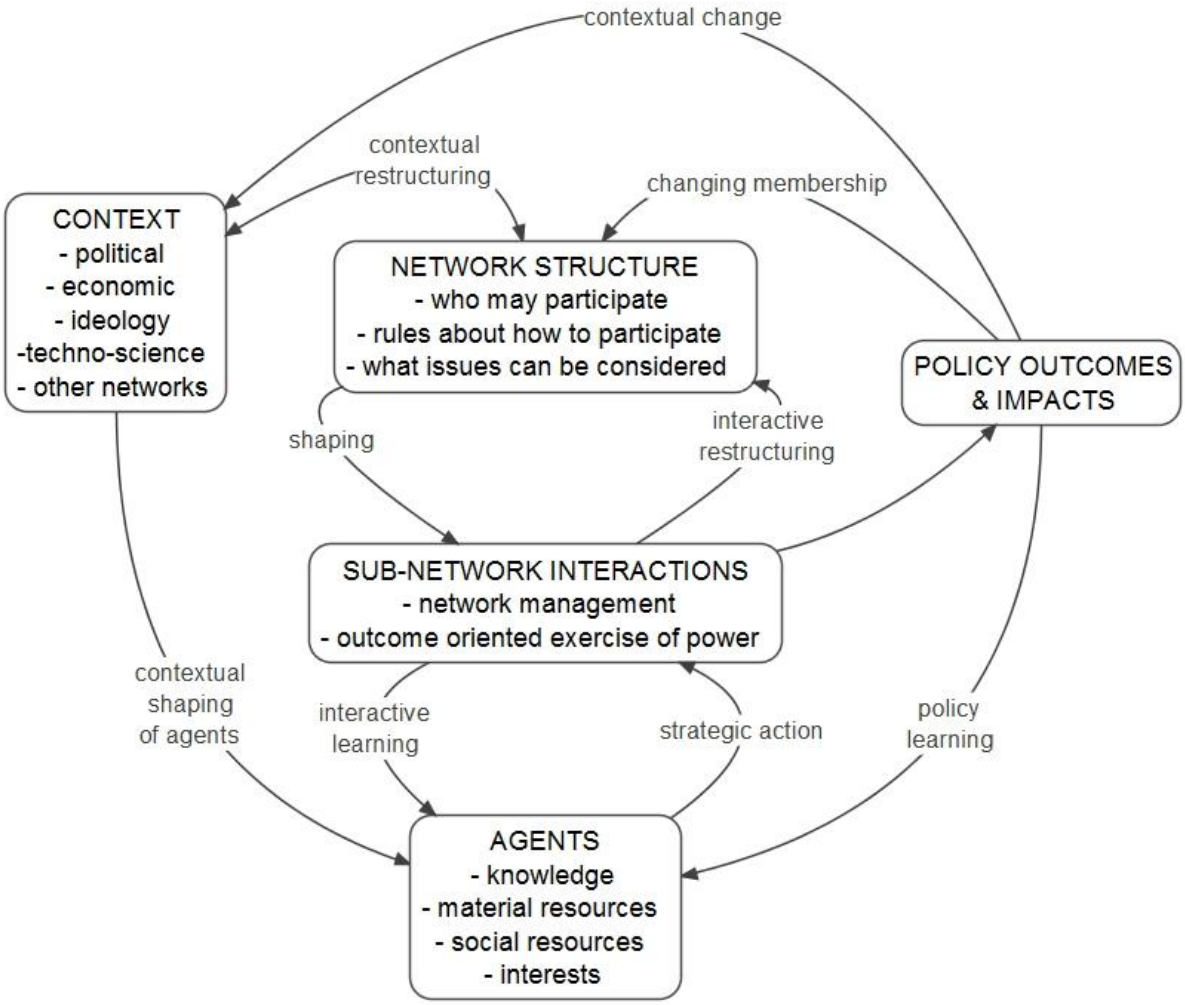
A. Future Governance Research

Each of the literatures has long histories that create significant diversity in their perspectives and findings. However, transferring ideas and perspectives across the literatures can create richer inquiry and understandings of emerging governance patterns. But this is challenging because the literatures often use the same language to conceptualize very different concepts, or very different language to describe and explain the same phenomenon. This is well exemplified by the very different uses of the concept of networks. In the policy science literature, there is an extensive debate on the meaning and utility of "policy networks" (Bevir & Richards, 2009; Borzel, 1998; Börzel, 1997; Dowding, 1995, 2001; Marsh & Smith, 2001), which acknowledges but barely

scratches the surface of the sociological debates on networks as conceptualized by the Latour, Callon, and Law (Bloor, 1999; Busch & Juska, 1997).

The clarity needed to integrate such diverse scholarship requires far more reading and study than was possible in this study alone. Yet the policy networks framework that simplified the morass of actors and institutions engaged in governance also holds potential for organizing the morass of scholarship on governance. To reiterate, the conceptual framework of policy networks is shown in figure 4.

Figure 4: Conceptual Framework of Policy Network Variables



While the areas of scholarship as a whole tend to flood light on the entire network framework, individual studies turn spotlights on different components. For instance, administrative law

scholarship is often concerned with the interactions between network structure and network interactions variables within the network framework and the consequences for policy outcomes. For instance, (McGarity 2003; Wagner, Barnes, and Peters 2011) examine the ways stakeholders participate in and influence the rulemaking process. Similarly, the studies on accountability and ossification are concerned with how network structures impact the networks interactions (McGarity 1992; Yackee and Yackee 2012).

Much of the agrifood governance literature looks at the relationships between context, agent, and network interaction variables. For instance, (Busch 2010a; Cheshire and Lawrence 2005) examine how contemporary governance patterns create a context that has restructured states roles in regulatory networks, resulting in new forms of interactions between state and non-state actors within regulatory networks. Yet related studies, such as (Hatanaka and Busch 2008), focus much more closely on the network structures and network interactions.

Thus studies from diverse disciplines could be organized and compared using a chart as shown in Table 2. This chart allows one to examine overlaps and disconnects between studies from different literatures and how each offers unique insights into a component of the governance process.

Table 2: Organization of Governance Studies

Framework variable → / **Article**	Context	↑ Contextual restructuring	↑ Contextual shaping of agents	Network structure	↑ Shaping	Sub-network interactions	↑ Interactive restructuring	↑ Interactive learning	Agents	↑ Strategic action	Policy outcomes	↑ Policy learning	↑ Contextual change	↑ Changing membership
(McGarity 2003)				X	X	X			X	X	X			
(Wagner et al. 2011)				X	X	X			X	X	X			
(McGarity 1992)				X	X	X					X			
(Yackee and Yackee 2012)				X	X	X					X			
(Busch 2010)	X	X	X	X					X	X				
(Cheshire and Lawrence 2005)	X	X	X	X		X			X	X				
(Hatanaka and Busch 2008)				X	X	X								

However, individuals studies also tend to vary markedly about the normative concern they are raising. For instance, (Mashaw 2005; Wagner et al. 2011) focus on mechanisms for producing accountability while (Fuchs, Kalfagianni, and Havinga 2011) examine legitimacy and accountability and (Campbell and Heron 2007) focuses only on how legitimacy is constructed. Further, the studies each use distinctly different methods for empirically evaluating how normative values operate in the different regimes. Thus, categorizing studies by their democratic normative concerns would allow for further comparison of the theoretical and methodological insights different disciplines offer.

Thus, one could organize studies and research findings along two domains – the point in the policy network framework that they focus on, and second, the normative value they are concerned with.

This provides a graphical representation that can help place individual studies in the larger intellectual context, which I believe can augment the conceptual framework offered by Eberlein et al. (2014). While it is difficult for one study to capture the entire complexity of governance changes, I think this is a way to keep track of which piece of the puzzle any given study is working on while also retaining a framework for referring to the numerous other bodies of literature that connect to and should inform any single study's findings.

Future research should explore the intellectual utility of this framework. The first step is a pair of literature review papers. The first paper needs to review and clarify the linguistic confusion created by bringing so many literatures together. Most importantly, the paper needs to address and clarify the meaning of terms such as 'networks' and 'governance' and the multiple ways they are used together and overlap. Another paper would organize the existing scholarship according to the governance networks framework and grid to demonstrate the utility of the modified policy network framework for synthesizing diverse governance literatures.

Having done this, further research can be designed to make use of the framework. Studies might examine agrifood governance as it is occurring at multiple levels and across geographies, apply the framework to other policy domains such as forestry and labor, and apply additional methods. The methods from this study can be improved by refining the variables and codes for qualitative analysis and adding quantitative methods such as social network analysis. The literature review may also suggest further methods for more quantitative comparison of the various policy networks. For instance, (Fuchs et al. 2011) and (Wagner et al. 2011) both present alternative measures for evaluating the accountability of particular governance processes, which could be applied to more networks and then the comparison could be situated among other governance studies by using the governance networks framework.

B. Future Governance Praxis

Administrative Law Practitioners

While the scholarship on administrative law debates the ossification of administrative law and attempts to conceptualize new ways to achieve democratically legitimate agency action, agency administrators must continue muddling through.

The scholarship is optimistic that agencies just need to figure out how to develop flexible, dynamic regulations in order to manage the complexity of contemporary systems and play a role in transitioning into newer, stronger forms of interconnected regulatory networks. But given the imbalanced political dynamic evident in the writing of the authorizing legislation and further aggravation of power imbalances through the proliferation and subsequent partial harnessing of private regulatory networks, this seems overly optimistic.

In the meantime, for all that traditional administrative law has its problems, the examination of the FSMA showed one benefit: committed agency action to extensive engagement, even if time consuming, is possible, and can achieve a perceived sense of legitimacy and accountability with an array of conflicted stakeholders. As laws increasingly put agencies in positions of coordinating and collaborating with private regulatory networks, like the FSMA has done to the FDA, expanding the notice and comment procedures to create transparency and broad stakeholder participation can help the agency gain legitimacy as an arbiter among the networks. Even as this creates tensions and complicates the agency's tasks, it offers a pragmatic way forward for agencies to establish systems of exercising meta-governance oversight of the private regulatory networks.

Agrifood Systems Change

For proponents of agrifood systems change, this intellectual pursuit may contribute to finding effective leverage points for tipping the system toward sustainability and justice and provide better

understanding of why past efforts have produced disappointing results. Unfortunately, this analysis reveals they are trapped between a rock and a hard place.

Corporate and capitalist dominance of state policy making has, thus far, been incredibly difficult for civil society to overcome. Even in the case of relatively strong and successful civil society sectors such as the consumer groups, achieving regulatory change was not possible until industry interests aligned with the consumers groups. For emergent groups such as alternative agrifood systems advocates, despite having achieved success at being recognized as potentially powerful, the prospects of changing state action appear dim. Further, achieving influential power over state action has little meaning if nothing is done to restructure global networks of regulation and roll-back the neoliberal projects that currently undergird the private regulatory activity.

An alternative tack that has been pursued so far has been to contest corporate control in the private realm, through creation of alternative agrifood standards and attempting to build alternative markets and channels of distribution. However, this has been critiqued as simply re-perpetuating the neoliberal logics that have created the problems in the first place.

Another approach is to forego attempting to change contemporary, dominant governance patterns and to focus instead on creating new forms of interaction and exchange that enact more just, sustainable values. Exploration of this approach was rejected at the start with the premise that achieving genuine change inherently necessitates addressing policy and governance. Nothing in this study has suggested a reason to reject this premise, other than the evidence that the current apparent options for achieving policy change have been, thus far, ineffective. And so, the contribution of this study to praxis of food systems change is simply to add to the cacophony of critiques.

C. Conclusions on Prospects of Agrifood Systems Change

Using the enactment and rulemaking of the FSMA as a case study, this research asked questions about the roles and capacities of different stakeholders to meaningfully influence the decisions that

critically impact their lives. The questions were concerned with the impacts of changing governance patterns on different actors' ability to meaningfully influence agrifood systems governance. If, as proponents of alternative agrifood systems seem to agree, the system is unacceptably broken, what prospect is there for change? If pursuing change is a pressing necessity, regardless of the possibilities of success, what are the promising avenues for change?

The research concludes that the enactment and rulemaking of the FSMA largely reinforces corporate power, globalized food systems and neoliberal ideologies. The law sets the U.S. down a path of public-private co-regulation, thereby expanding and legitimating the role of private regulators and industry in governing food safety. It produces neoliberalism by putting the state in a position of supporting and promoting food safety governance through market based mechanisms and facilitating global trade.

The final provisions in the FSMA strengthen the FDA's authorities, but put the agency in a position of trying to navigate a line between independence from and collaboration with private regulatory networks, while being responsive to a variety of conflicted stakeholders. The agency's efforts to fulfill democratic norms of legitimacy and accountability are in tension with its incentives and responsibility to coordinate and harmonize with the other policy networks. Subjected to traditional administrative procedure law, the agency is ill equipped to handle the complex co-regulatory task it is assigned.

Yet alternative agrifood systems advocates also used the process to successfully contest corporate agendas and are exploiting governance networks to pursue their interests. Nonetheless, scholarly critiques that contestation activity often reinforce neoliberal ideologies and fail to effectively reform policies that support the current corporate food regime hold true in this case. In this case, alternative agrifood activists were forced to use the same political tactics to oppose the law and regulations that are typical of industry efforts to evade regulation. At the same time, state and civil

society initiatives to educate and help producers achieve compliance with private regulatory systems look depressingly like cooptation into neoliberal market governance mechanisms.

There is general consensus that these sorts of overlapping regulatory networks will characterize regulation and governance for the foreseeable future, and government institutions will retain authorities that will guarantee their continued exigency as regulatory actors. The research showed that actors' participation in these multiple networks can critically impact policy formation and choices. The documented processes and outcomes highlight the importance of monitoring and participating in the proliferating policy networks. Yet the proliferation of policy networks aggravates power imbalances and further marginalizes resources constrained actors' capacities to meaningfully participate in governance choices that affect their lives. This seemingly undermines transparency, inclusiveness, and accountability in the overall system.

Nonetheless, there is a possibility that the proliferation of governance networks could enhance regulatory effectiveness or lead to more innovative forms of legitimate and accountable forms of governance. Critical scholarship and self-reflexive praxis, examining and understanding the short-term successes and long-term consequences of particular strategies, will be critical to shifting contemporary governance onto a path where actors have meaningful opportunities to participate in the governing of their lives.

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